Luminex®

Luminex 100™ IS
User Manual Version 2.3

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Luminex® 100™ IS User Manual Version 2.3

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EULA PN: 89-30000-00-070

Contents

1 Introduction

About This Manual

This manual provides you with information to understand and use the Luminex® 100™ IS system. It consists of multiple chapters and appendices that take you from this introduction to complete system operation.

The manual's text and figures offer examples when necessary. Procedures are presented as step-by-step instructions. Glossary and index sections assist as references.

The conventions in this manual assume that the reader has a basic familiarity with computers, xMAP® technology, and a knowledge of Microsoft® Windows® software. We typically document the common methods of accessing a command, such as from the main menu bar, from the toolbar, and from menus that appear when you right-click an area of the screen. Refer to the Glossary appendix for unfamiliar terminology.

The Luminex 100 IS 2.3 System

The Luminex 100 IS 2.3 system is a benchtop system consisting of the Luminex 100 analyzer, computer, monitor, keyboard, mouse, Luminex XY Platform instrument (Luminex XYP™), Luminex Sheath Delivery System (Luminex SD™), software, barcode reader, sheath and waste containers, and xMAP technology reagents.

Intended Use

The Luminex software is designed to use xMAP technology with assay kits available through kit manufacturers.The Luminex 100 IS 2.3 system performs a wide range of xMAP technology-based laboratory tests, measuring biomolecular reactions on the surface of xMAP microspheres. This system is intended for indoor, general laboratory use.

Technical Support

Luminex Technical Support representatives are ready to help you, particularly when the system or software cause any questions or problems. If the question or problem relates to materials from the assay kit, you should contact the kit provider directly.

Luminex Technical Support is available to users in the U.S. and Canada by calling 1-877-785-BEAD (-2323) between the hours of 7:00 a.m. and 7:00 p.m. Central Time, Monday through Friday. Users outside of the U.S., Canada, Europe can contact us at +1 512-381-4397 between the hours of 7:00 a.m. to 7:00 p.m. Central Time, Monday through Friday. Inquiries may also be sent by email to support@luminexcorp.com.

Luminex Technical Support is also available to users in Europe by calling +31-162408333 between the hours of 8:30 and 5:30, Central European Time, Monday through Friday. Email inquiries in Europe can be sent to supporteurope@luminexcorp.com.

Luminex Website

Additional information is available on the Luminex website. Search on the desired topic or navigate through menus. Also, review the website's FAQ section.

- To access Luminex website FAQ section:
  In your browser's address field, enter:
  http://luminexcorp.custhelp.com. This address takes you directly to the FAQ section.

2 Safety

Symbols

Please become familiar with the information in this chapter before using the equipment. Do not perform procedures on your Luminex 100 IS 2.3 system that are not specifically contained in this manual, unless you are directed to do so by Luminex Technical Support.

These symbols describe warnings, cautions, and general information used in the operation of this instrument. These symbols are further defined under “Safety Precautions.”

Number	Symbol	Description	Number	Symbol	Description
1	~	Alternating current (ac)	7		Warning (refer to manual)
2	⏚	Protective ground	8		Warning (refer to manual)
3	|	On	9		Warning (refer to manual)
4	○	Off	10		Warning (refer to manual)
5	SN	Serial number	11		Warning (refer to manual)
6		Warning (refer to manual)			

Warnings and Notes

Informational notes and warnings appear in this manual.

Note: A note provides general helpful information. No safety or performance issues are involved.

Caution: This message is used in cases where the hazard is minor or only potential hazard is present. Failure to comply with the caution may result in potentially hazardous conditions.

Warning: This message is used in cases where danger to the operator or to the performance of the instrument is present. Failure to comply with the warning may result in incorrect performance, instrument failure, invalid results, or hazard to the operator.

Danger: This message is used in cases where significant risk of serious injury or death is present.

Safety Precautions

Read the following safety information before setting up or using the Luminex 100 IS 2.3 system. A user should be present during operation. This system contains electrical, mechanical, and laser components which, if handled improperly, are potentially harmful. In addition, biological hazards may be present during system operation. Therefore, we recommend that all system users become familiar with the specific safety advisories below, in addition to adhering to standard laboratory safety practices. The protection provided by the equipment may be impaired or the warranty voided if the system is used in a manner not specified by the instructions or by Luminex Corporation.

This caution label appears on the back of the Luminex 100 analyzer and on the Luminex XYP instrument.

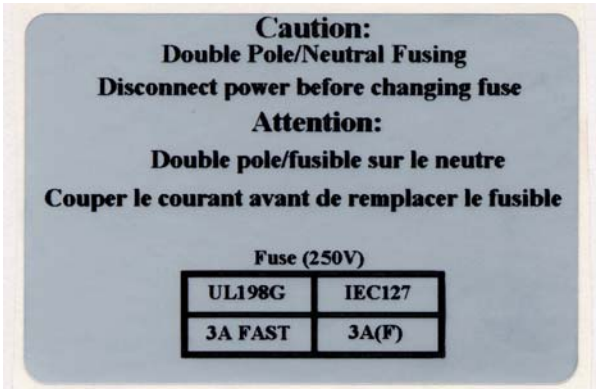


Figure 2-1 Fuse Caution Label

Do not perform any maintenance or cleaning of the system's electrical components, with the exception of replacing fuses.

This label appears on the back panel of the Luminex 100 analyzer and on the back panel of the Luminex XYP instrument.

Figure 2-2 CE Label

The Luminex 100 analyzer and the Luminex XYP instrument comply with European Union (EU) safety requirements and, therefore, may be marketed in the Europe Single Market.

This voltage label appears on the back of the Luminex 100 analyzer:

Figure 2-3 Luminex 100 Serial Number Label

The Luminex 100 analyzer has been tested by Underwriter Laboratories, Inc.® (UL).

The following label appears on the back of the Luminex XYP instrument.

Figure 2-4 Luminex XYP Serial Number Label

The Luminex XYP instrument has been tested by UL.

FCC Label

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Fluidics

This system contains fluidics. In the event of a fluid leak, turn off all power to the system and disconnect all power cords. Remember that the on/off switch is not a disconnect means; the power cord must be removed from the outlet. Contact Luminex Corporation for further information.

You must monitor waste levels manually. Do not allow the waste container to overflow! Empty the waste container each time the sheath fluid container is filled. Do not place the waste container on top of the instrument.

Warning: If biological samples have been tested with the system, use your standard laboratory safety practices when handling system waste.

Luminex 100 Analyzer Laser

The Luminex 100 IS system classifies per FDA 21 CFR 1040.10 and 1040.11 as a Class II laser product consisting of a Class I laser product (Luminex 100 analyzer) and a Class II laser product (barcode reader).

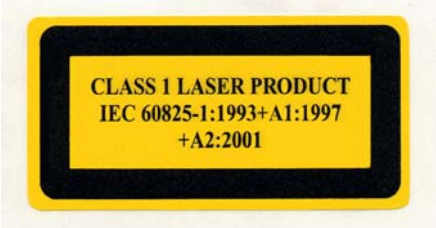


Figure 2-5 Laser Product Class Label

United States and international regulations require the following warnings to appear on the instrument during operation and maintenance.

This label appears on the back panel of the Luminex 100 analyzer.

Figure 2-6 Laser Radiation Caution Label

Under NO circumstances should you remove the Luminex 100 analyzer cover! When performing routine maintenance, turn power to the Luminex 100 analyzer OFF and the disconnect the power cord.

All laser apertures are located within the Luminex 100 analyzer and are contained within a protective housing. This label appears on the optics cover within the Luminex 100 analyzer.

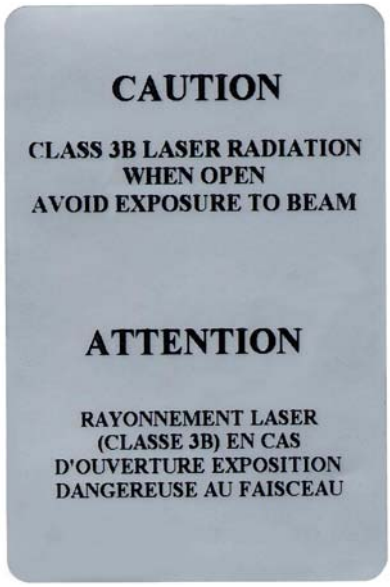


Figure 2-7 Laser Class Label

Warning — Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Attention — L'utilisation des commandes ou réglages ou l'exécution des procédures autres que celles spécifiées dans les présentes prescriptions peuvent entraîner d'une exposition à un rayonnement dangereux.

This label appears above the laser apertures located inside the optics enclosure inside the Luminex 100 analyzer.

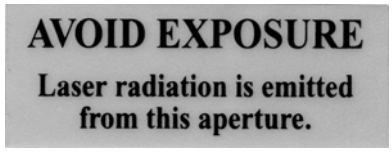


Figure 2-8 Avoid Exposure Label

Barcode Reader Laser

This label is attached to the barcode reader.

Figure 2-9 Barcode Reader Laser Label

Do not stare into the beam or shine it into other people's eyes.

Mechanical

Note: Access doors must be closed while operating the Luminex 100 analyzer; the operator must be present during operation.

Warning: During operation, this system contains exposed, moving parts. Risk of personal injury is present. Observe all warnings and cautions.

Warning: During operation, this system contains exposed, moving parts which could result in puncture hazard. Risk of personal injury is present. Keep hands and fingers away from the Luminex XYP instrument slot during operation.

Warning: During operation, this system contains exposed, moving parts which could result in pinch point hazard. Risk of personal injury is present. Keep hands and fingers away from the Luminex XYP instrument slot during operation.

Biological

Warning: Human and animal samples may contain biohazardous infectious agents.

Where exposure (including aerosol) to potentially biohazardous material exists, follow appropriate biosafety procedures and use personal protective equipment, such as gloves, gowns, laboratory coats, face shields, or mask and eye protection, and ventilation devices.

Observe all local, state, and federal biohazard handling regulations when disposing of biohazardous waste material.

Heat

Warning: The heater plate of the Luminex XYP instrument may be hot and could cause personal injury if touched. Do not touch the heater plate.

Blue Indicator Light

The blue light above the Luminex 100 analyzer sample arm indicates the on/off status of the Luminex 100 analyzer, and is harmless. The blue light-emitting diode (LED) does not emit light in the UV spectrum.

Decontaminating the Luminex 100 Analyzer for Return Shipment

Luminex Technical Support will give you a Return Material Authorization (RMA) number if they direct you to return the system. They will explain how to return the system according to Luminex procedures.

The accessible surfaces and the internal fluidics system must be sanitized and decontaminated before returning the analyzer. This is particularly important when biohazardous samples have been run. Make a copy of this page to fill out and return with the system.

Complete the following checklist, signed and dated, and return it with the Luminex 100 analyzer.

Note: It is the user's responsibility to decontaminate the analyzer before shipment.

- ☐ 1. Remove all specimens, disposables, and reagents from the system.
- ☐ 2. Disconnect the sheath line going from the SD system to the analyzer.
- ☐ 3. Connect a sheath bottle filled with a solution of 10% to 20% household bleach and water to the analyzer.
- ☐ 4. Sanitize the system using the **Sanitize** command on the main screen of the system. Follow this by washing twice with distilled water.
- ☐ 5. Disconnect the system from AC power by turning off the power switch on the rear of the system, then unplugging the analyzer power cord from the wall source.
- ☐ 6. Disconnect the SD system and waste and sheath containers.
- ☐ 7. Rinse the waste container with 10% to 20% household bleach solution and drain.
- ☐ 8. Wash all exterior surfaces with a mild detergent, followed by a 10% to 20% bleach solution.
- ☐ 9. Open both front doors of the analyzer and clean all accessible surfaces with mild detergent followed by a 10% to 20% bleach solution.
- ☐ 10. Pack the system within a biohazard bag, place it in the corrugated box, then insert it in its original packaging or an approved shipping container. Attach this checklist to the top of the corrugated box prior to packaging in the crate.

Was there an internal leak in the system? ☐ Yes ☐ No

Print Name: _____

Signature: _____

Date: _____ Instrument Serial No. _____

3 The System

Theory of Operation

Luminex 100 IS technology is based on flow cell fluorometry with Luminex-developed innovations. The fluidics, optics, robotics, temperature control, software, and xMAP microspheres work together to enable simultaneous analysis of up to 100 analytes in a single test sample. Assay analysis requiring temperature control is provided through the Luminex XYP instrument heater block.

There are two fluidics paths in the Luminex 100 analyzer. The first path involves a syringe-driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The syringe-driven system transports a specified volume of sample from a sample container to the cuvette. The sample is injected into the cuvette at a steady rate for analysis. Following analysis, the sample path is automatically purged with sheath buffer by the second fluidics path. This process removes residual sample within the tubing, valves, and probe. The second fluidics path is driven by positive air pressure and supplies sheath fluid to the cuvette and sample path.

Sheath fluid is the delivery medium of the sample to the optics component. The analysis sample is acquired using a sample probe from a 96-well microtiter plate via the Luminex XYP instrument and injected into the base of the cuvette. The sample then passes through with sheath fluid at a reduced rate resulting in a narrow sample core to ensure that each microsphere is illuminated individually. The sample injection rate is such that the xMAP microspheres are introduced to the optics path as a series of single events. The Luminex SD system lets you run samples continuously without refilling sheath bottles. It automatically draws sheath from a non pressurized bulk sheath container to constantly maintain a reservoir

of pressurized sheath fluid. A single 20 liter sheath container provides enough fluid for 48 hours or more of normal operation.

The optics assembly consists of two lasers. One laser excites the dye mixture inside the xMAP microspheres and the second laser excites the fluorosphere bound to the surface of the xMAP microspheres. Avalanche photo diode detectors measure the excitation emission intensities of the color coding classification dye mixtures inside the xMAP microspheres and a photomultiplier tube detects the excitation emission intensity of the reporter molecule bound to the surface of the xMAP microspheres. High speed digital signal processors and advanced computer algorithms provide analysis of the xMAP microspheres as they are processed through the Luminex 100 analyzer. Results of the analyses are processed and provided in a report format.

Hardware

The Luminex 100 IS system includes the following hardware:

- Luminex 100 analyzer
- Computer (PC), monitor, and accessories
- Luminex XYP instrument
- Luminex Sheath Delivery System (Luminex SD™)
- Power cables
- Alignment guide
- Two long sample probes
- Luminex XYP instrument sample probe
- Reservoir
- Shield
- Heater block
- Sheath fluid container
- Waste container
- Sheath fluid line
- Air line
- Sheath fluid intake line
- Communications: 1 serial communication cable
- Communications: 1 USB communication cable
- Communications: 1 CANBUS communication cable (short cable)
- Barcode reader
- Sample probe height alignment kit
- 3/32 Hexdrive, Balldriver wrench

xMAP Technology Reagents

- Classification calibration microspheres (CAL1)
- Reporter calibration microspheres (CAL2)
- Classification control microspheres (CON1)
- Reporter control microspheres (CON2)
- Sheath fluid

Required Laboratory Reagents

- Household bleach
- 70% isopropanol or 70% ethanol
- Mild detergent

Luminex 100 IS 2.3 Software

Luminex 100 IS 2.3 software provides complete control of the system and performs data analysis. Your Luminex 100 IS 2.3 system is preloaded with the Luminex software. However, we supply a software CD should you need to reinstall the software.

This software requires a dedicated system. Unauthorized additional software is prohibited and may result in improper operation of the system.

Luminex 100 IS Performance Specification

Speed

- Speed: greater than or equal to1.7 GHz Intel® Pentium® IV processor with 256 MB RAM
- USB communications link for fast data transfer
- Automatic transfer of assay templates and new reagent information into the system via a 3½” diskette or large capacity read/write CD
- Installation: < 4 hours
- System calibration: < 10 minutes
- System controls: < 10 minutes
- Barcode reader entry of sample IDs
- Automatic post-analysis
- Analyze one 96-well plate/hour depending on manufacturer’s kit
- Up to 100 xMAP microsphere sets per sample
- Sheath flowrate: 90 µL/sec ± 5 µL

- Sample injection rate into detector area: 1 µL/sec ± 0.05 µL
- System warmup: 30 minutes. Systems that remain inactive for at least four hours will require a warm-up to restart the lasers. After acquiring sample, running system calibrators, running system controls, and warming up the instrument, the system resets the four-hour internal clock.

Accuracy and Precision

- Sample uptake volume: ± 5%
- Classification of xMAP microspheres: > 80%
- Misclassification of xMAP microspheres: < 0.5% - may vary by xMAP microsphere product lines. Refer to the specific product information sheet for further details.
- Temperature control: 0°C to + 2°C of target
- Internal sample carry over: < 0.9%
- Soluble background fluorescence emission at 575 nm automatically subtracted from fluorescence intensity values

Sensitivity

- Detect 1000 fluorochromes phycoerythrin (PE) per xMAP microsphere
- Reporter channel dynamic range: 3.5 decades of detection

Capacity

The specifications below reflect minimum capacity values:

- 10 GB hard drive
- Store data for up to 240,000 test results
- 1.4 MB 3½" diskette
- 100 MB read/write CD ROM
- Analyze multiple 96-well plates per batch
- Analyze multiple assay templates per plate
- Distinguish a minimum of 1 to a maximum of 100 unique xMAP microsphere sets in a single sample
- Detect and distinguish surface reporter fluorescence emissions at 575 nm on the surface of 1-100 unique xMAP microspheres sets in a single sample
- Sample core: 15-20 µm core at 1 µL/sec. sample inject rate
- Maintain samples at a constant temperature from 35°C to 55°C (95°F to 131°F)
- Automatic sampling from a 96-well plate
- Start sampling from any well position
- Sheath container and waste container hold enough volume to run up to two 96-well plates between refills
- Microtiter plates with 96 wells must be compatible with the Luminex XYP instrument plate holder. The following microtiter

plate types are compatible with the Luminex XYP instrument plate holder: flatbottom, conical, round, filter bottom, half plates [overall height no more than 0.75” (19 mm)], any color

- Microtiter plates with 96 wells must be compatible with Luminex XYP instrument heater block temperature from 35°C to 55°C (95°F to 131°F) when performing heated assays and using the heater block

Luminex 100 Analyzer General

- Indoor use only
- Operating temperature: 15°C to 30°C (59°F to 86°F)
- Humidity: 20% to 80%, noncondensing
- Altitude: Operation up to 2400 m (7874 ft.) above mean sea level
- Physical dimensions: 43 cm (17 inches) W x 50.5 cm (20 inches) D x 24.5 cm (9.5 inches) H
- Weight: maximum of 25 kg (60 lbs.)
- UL installation category: UL Installation Category II, as defined in Annex J of UL 61010A-1
- Pollution degree: UL Pollution Degree 2, as defined in Section 3.7.3.2 of UL 61010A-1
- Shipping and storage: The allowable shipping and storage temperature and humidity ranges are 0°C to + 50°C and 20-80% noncondensing, respectively
- Input voltage range: 100 - 120 V~ and 200-240 V~ ± 10%, 1.4 Amp, 47-63 Hz.
- AC inlet fuse: 3 Amp, 250 V~, fast acting

Optics

- Reporter laser: 532 nm, nominal output 10-16.5 mW, maximum 500 mW, frequency-doubled diode; mode of operation, continuous wave (CW)
- Classification laser: 635 nm, 9.1 mW ± 6%, maximum output 25 mW, diode; mode of operation, continuous wave (CW)
- Reporter detector: Photomultiplier tube, detection bandwidth of 565-585 nm
- Classification detector: Avalanche photo diodes with temperature compensation
- Doublet discrimination detector: Avalanche photo diodes with temperature compensation

Fluidics

- Sheath flow rate 90 µL ± 5 µL/second
- Cuvette: 200 micron square flow channel
- Sample injection rate: 1 µL/second
- Sample uptake volume: 20-200 µL

Electronics

- Reporter channel detection: A/D resolution 14 bits
- Communications interface: USB
- Luminex XYP instrument, communications interface: RS 232

Luminex XYP Instrument General

- Ambient temperature: 15°C to 30°C (59°F to 86°F)
- Humidity: 20% to 80%, noncondensing
- Altitude: operation up to 2400 m (7874 ft) above mean sea level
- Physical dimensions: 44 cm (17.25 inches) W x 60 cm (23.5 inches) D x 8 cm (3 inches) H
- Weight: 15 kg (33 lbs.)
- UL installation category: UL Installation Category II, as defined in Annex J of UL 61010A-1
- Pollution degree: UL Pollution Degree 2, as defined in Section 3.7.3.2 of UL 61010A-1
- Heater operating range: 35°C to 55°C (95°F to 131°F) with tolerance 0°C to +2°C
- Input voltage range: 100-240 V~ ± 10%, 1.8 Amps, 47-63 Hz
- AC inlet fuse: 3 A, 250 V~, fast acting

Luminex SD System General

- Ambient temperature: 15°C to 30°C (59° to 86°F)
- Humidity: 20% to 80%, noncondensing
- Altitude: designed to operate at up to 2400m (7874 feet) above mean sea level
- Physical dimensions: 20 cm (8 inches) W x 30 cm (11.75 inches) D x 24.75 cm (9.75 inches) H
- Weight: 9 kg (20 lbs)
- UL installation category: UL Installation Category II, as defined in Annex J of UL 61010A-1
- Pollution degree: UL Pollution Degree 2, as defined in Section 3.7.3.2 of UL 61010A-1
- Input voltage range: 100-240 V~ ± 10%, 0.4 Amps, 47-63 Hz
- AC inlet fuse: 2 Amp, 250 V~, time lag

PC Specifications

These specifications reflect minimum capacity values:

- Computer: an Intel Pentium IV or equivalent class PC, minimum speed 933 MHz
- Main memory: minimum of 256 MB
- Hard disk drive: 10 GB minimum storage capacity

Note: Contact Technical Support for additional operating system information

- Communications, parallel pointing device and serial ports: Minimum of 1 parallel, 1 PS/2 compatible pointing device, and 2 RS-232 compatible serial ports
- Communications, USB port: Minimum of one USB Version 1.1 compatible high speed port
- Read, write removable media: CDR/W-type drive, standard 1.44 MB 3.5-inch disk drive
- Operating system support: Microsoft® Windows® XP Professional (English language version)
- CE marked and UL listed
- Two-button mouse or equivalent
- Monitor: A minimum of 17-inch diagonal monitor
- Keyboard: a 104-key keyboard or equivalent
- Power cords: Power cords specific to the country of use are included in the system as required
- Power: 115-230 V~, 6 Amps, 50-60 Hz

Recommended Additional Equipment

Uninterruptible Power Supply (UPS)

Luminex highly recommends using an uninterruptible power supply (UPS) to protect your system from power outages. Choose one that can provide 1050 Watts for at least 45 minutes. The UPS should be UL listed, CSA certified, and CE marked when used internationally.

Surge Protector

If you do not use a UPS, use a surge protector. Choose a protector that meets your needs. Factors to consider include electrical environment, endurance, suppressed voltage rating, and method of protection. It should have six outlets, rated at least 1500 Watts, and be UL listed, CSA certified, CE marked for nondomestic use when used internationally.

Printer

Printer, HP LaserJet 2300 or available equivalent

Barcode Labels

Use the Code 128 barcode label type when scanning barcode labels into the system as patient identities.

Vortex

VWR product number 58816-121: Speed range 0-3200 rpm or equivalent

Bath Sonicator

Cole-Parmer® product number 08849-00: Operating frequency 55 kHz or equivalent

System Overview

The system consists of three subsystems: electronic, fluidic, and optical. The following section describes the user-accessible components of each subsystem.

Electronics

Power Input Module

The power input modules contain the on/off switch and fuses.

Communications Ports(SB9-PIN)

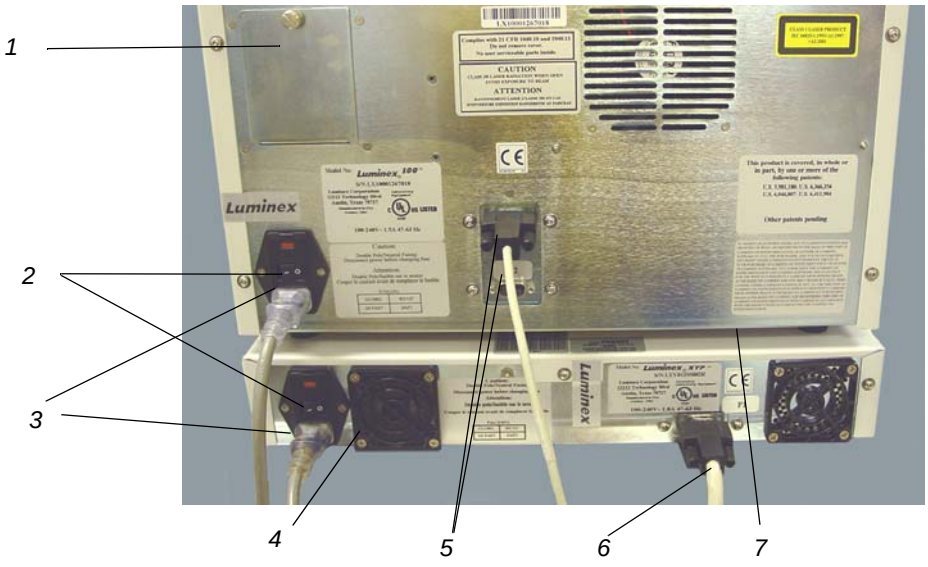
The communications port connects the Luminex 100 analyzer or the Luminex XYP instrument to the computer, and the Luminex SD system to the Luminex 100 analyzer.

Luminex 100 Analyzer Ventilation Filter

Located on the bottom of the Luminex 100 analyzer, the filter must be checked and cleaned as necessary. For proper ventilation, do not obstruct the area below and allow at least two inches (5 cm) of clearance around the Luminex 100 analyzer.

Luminex XYP Instrument Ventilation Filter

The XYP instrument ventilation filter cleans the air that cools the internal parts of the Luminex XYP instrument. See Figure 3-1.



1. Air intake filter access door
2. Power Switch
3. Power Input Module
4. XYP Ventilation Filter
5. Communication Ports (DB9)
6. XYP Communication Port (DB9)
7. Analyzer ventilation filter (on bottom of analyzer)

Figure 3-1 Back of the Luminex 100 Analyzer and Luminex XYP Instrument

Fluidics

Sample Arm

The sample arm transports the sample from the sample tube to the cuvette. The carriage drops to the microtiter well for sample retrieval.

Luminex XYP Instrument Sample Probe

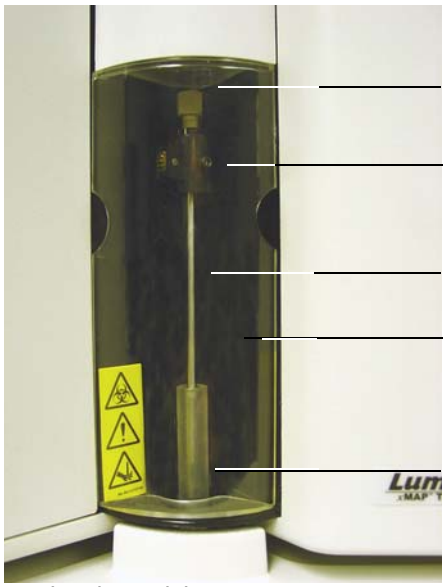
A stainless steel sample probe acquires the sample. A shorter probe is provided for shipping and troubleshooting.

Warning: During operation, this system contains exposed moving parts that can result in a puncture hazard. Risk of personal injury is present. Keep hands and fingers away from the sample probe. The shield should be in place.

Cheminert® Fitting

This fitting attaches the Luminex 100 analyzer sample arm tubing to the sample arm. Disconnect this fitting when you remove the sample probe. See Figure 3-2.

The alignment guide directs the sample probe into the Luminex XYP instrument.

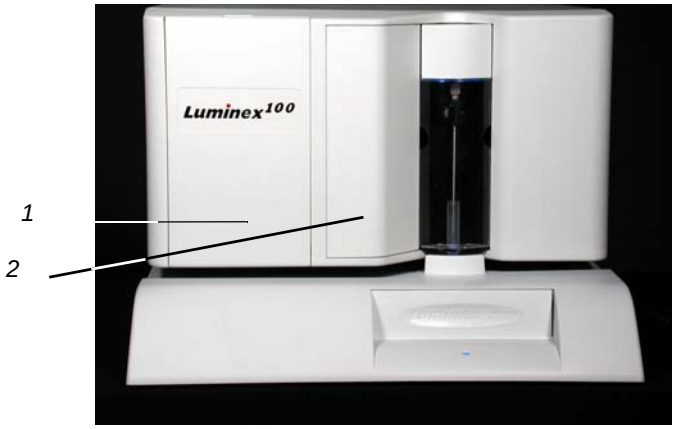


1. Cheminert Fitting
2. Sample Arm
3. Luminex XYP Instrument Sample Probe
4. Shield
5. Alignment Guide

Figure 3-2 Cheminert Fitting

Access Doors

The Luminex 100 analyzer has three access doors. Two of the access doors are on the front, and the third is on the back. The front left access door supplies access to the sheath filter. The front center access door supplies access to the syringe. The rear access door supplies access to the air intake filter. See Figure 3-3 and Figure 3-4.



1. Left door, access to service panel
2. Center door, access to syringe

Figure 3-3 Luminex 100 Analyzer Access Doors

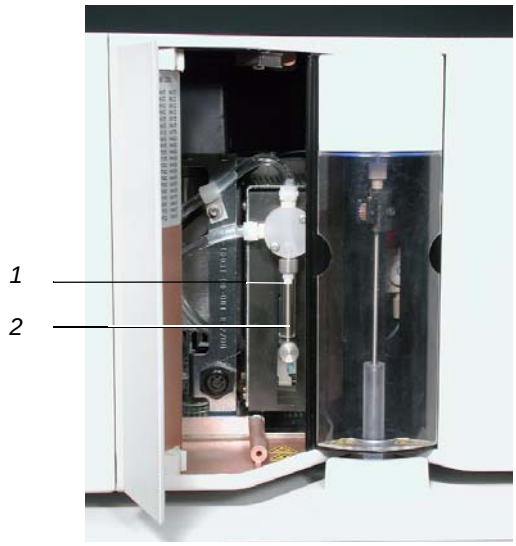
Air Intake Filter

A replaceable air intake filter cleans the air used to pressurize sheath fluid. This filter is enclosed behind an access door located on the back of the Luminex 100 analyzer. See Figure 3-4.

Figure 3-4 Air Intake Filter

Syringe

The syringe delivers a sample from the 96-well microtiter plate to the cuvette. See Figure 3-5.



1. Syringe Seal *2. Syringe*

Figure 3-5 Syringe and Syringe Seal

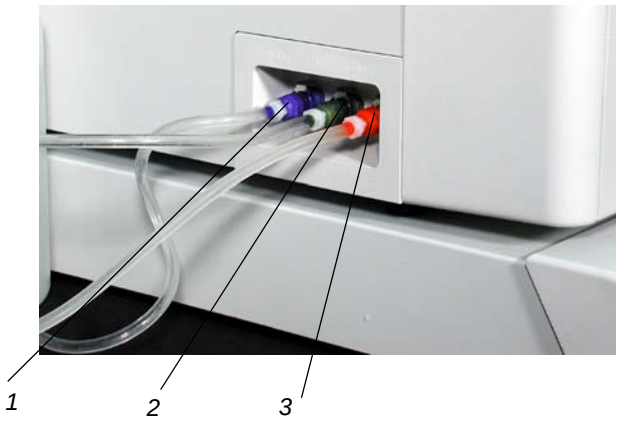
Sheath Filter

The sheath filter removes particles greater than ten microns in diameter from the sheath fluid. See Figure 3-6.

Figure 3-6 Sheath Filter

Air, Waste, and Sheath Fluid Connectors

The air, waste, and sheath connectors, located on the left side of the analyzer, connect to the SD system and waste fluid containers using clear tubing. The air connector is green, the sheath fluid connector is blue, and the waste fluid connector is orange. See Figure 3-7.



1. Sheath fluid connector (blue)
2. Air connector (green)
3. Waste connector (orange)

Figure 3-7 Air, Waste, and Sheath Fluid Connectors

Luminex Sheath Delivery System

Note: If you are not using the SD system, sheath fluid levels must be monitored manually. Check the sheath fluid level before starting a run or procedure.

For proper operation, place the Luminex SD system at the same level as the base of the Luminex XYP instrument. Do not put it on top of the Luminex 100 analyzer.

> **Warning:** If biological samples have been tested with the system, use your standard laboratory safety practices.

Waste Fluid Container

The waste fluid container receives waste from the system. The waste container should not be placed on top of the instrument.

> **Caution:** Waste levels must be manually monitored. Do not allow the waste container to overflow!.

Optical

The optical system consists of the optical assembly and the excitation lasers. The optical assemblies do not require manual adjustment by the user.

xMAP Technology Reagents

The xMAP technology reagent system consists of classification calibration microspheres, reporter calibration microspheres, classification control microspheres, and reporter control microspheres.

4 Basic Concepts

Background Information

xMAP technology is a versatile system that measures soluble analytes. The Luminex 100 IS system performs simultaneous, discrete measurements of multiple microsphere-based reactions from a single specimen aliquot. For more conceptual information, refer to *Practical Flow Cytometry,* 3rd edition, by Howard M. Shapiro, M.D. (New York: Wiley-Liss Inc., 1995).

Fluidics

There are two fluidic paths in the Luminex 100 analyzer. The first path involves a syringe-driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The syringe-driven system transports a specified volume of sample from a sample container to the cuvette. The sample is injected into the cuvette at a steady rate for analysis. Following analysis, the sample path is automatically purged with sheath fluid by the second fluidics path. This process effectively removes residual sample within the tubing, valves, and probe. Approximately 160 µL of sheath fluid is dispelled into each well following sample acquisition. The second fluidics path is driven under positive air pressure and supplies sheath fluid to the cuvette and sample path.

Excitation

The excitation system in the Luminex 100 analyzer involves two solid-state lasers. A reporter laser excites fluorescent molecules bound to biological reactants at the xMAP microsphere surface, and a classification laser excites fluorochromes embedded in the xMAP microsphere. The lasers illuminate the xMAP microspheres as they flow single-file through the cuvette. RP1 refers to the excitation wavelength. CL1 and CL2 refer to the dyes embedded in the microsphere. DD refers to the channel that discriminates against doublets based on size.

Photodiodes and a photomultiplier tube receive fluorescent signals from xMAP microspheres. The Luminex 100 analyzer digitizes the waveforms and delivers the signals to a digital signal processor (DSP). Proprietary algorithms function with the DSP to greatly increase sensitivity.

xMAP Microspheres

The xMAP microspheres are highly uniform, polystyrene particles that have been crosslinked during polymerization for physical and thermal stability. Varying amounts of fluorochromes embedded within each xMAP microsphere give each xMAP microsphere set an unique fluorescent signal. To ensure the stability of this signal, it is essential to protect the microspheres from light**.** Follow the product information sheet instructions for storage procedures for xMAP microspheres and assay kits.

Calibrator xMAP microspheres are used to normalize the settings for the reporter channel, both classification channels and the doublet discriminator channel for the Luminex 100 analyzer.

The control xMAP microspheres are used to verify the calibration and optical integrity of the system.

Software Overview

This section provides a brief overview for using the Luminex 100 IS 2.3 software.

With the Luminex 100 IS 2.3 software, you work with assay kits provided by a kit manufacturer. A template may be included with each kit that is imported into the software. The template includes a sequence of commands required for the assay.

Once you select the template, you enter sample data into a “batch.” Sample input can be done quickly with either the keyboard or a barcode scanner. A batch can include as many samples as you have for the assay and can include multiple microtiter plates. You can even group multiple batches together into a multi-batch for efficient processing. You can process a batch immediately or choose to archive the batch for testing later.

As testing proceeds through the plate, you will see the display update to show the wells that have been processed. Progress is shown in both graphic and tabular form.

System calibrators and controls are provided as part of the system. Calibrate at least once monthly, when the delta calibration (dCAL) temperature changes by ±3 degrees, or if the system is powered off or moved. You must run system controls following calibration and as often as you like to ensure that your system continues to operate optimally.

The software provides you with a variety of reports.

- Analyte Reports provide batch results grouped by the test in a batch.
- Patient Summary reports provide batch results grouped by each patient or unknown in a batch.
- Clinical Patient reports provide a breakdown of samples according to the test analysis with that sample.
- Maintenance Reports provide a history of all maintenance operations performed during a specified period of time.
- Calibration Trend reports provide results of calibration commands performed over a specified time period.
- System Control Trend Reports provide results of system controls performed over a specified time period.
- Batch Summary Reports provide batch information in a sample versus test grid format.
- Quality Control Reports track the trends of assay controls over a period of time

These reports let you look at specific details regarding the samples you process through the Luminex 100 IS 2.3 software and system operation.

System tools help you monitor the system including a display showing real-time system property values and a message log. Errors are shown in the message log and also on your reports. You can even add comments to specific results in some of these reports.

To keep track of your reagents, the Luminex 100 IS 2.3 software stores lot numbers, expected values, and expiration information.

A comprehensive set of self-diagnostic tests ensure that your system is working correctly. These tests are performed at startup and can be performed at any time. If any problem is detected, an error message appears in the message log to inform you.

5 Using Luminex 100 IS 2.3 Software

Luminex 100 IS 2.3 Software

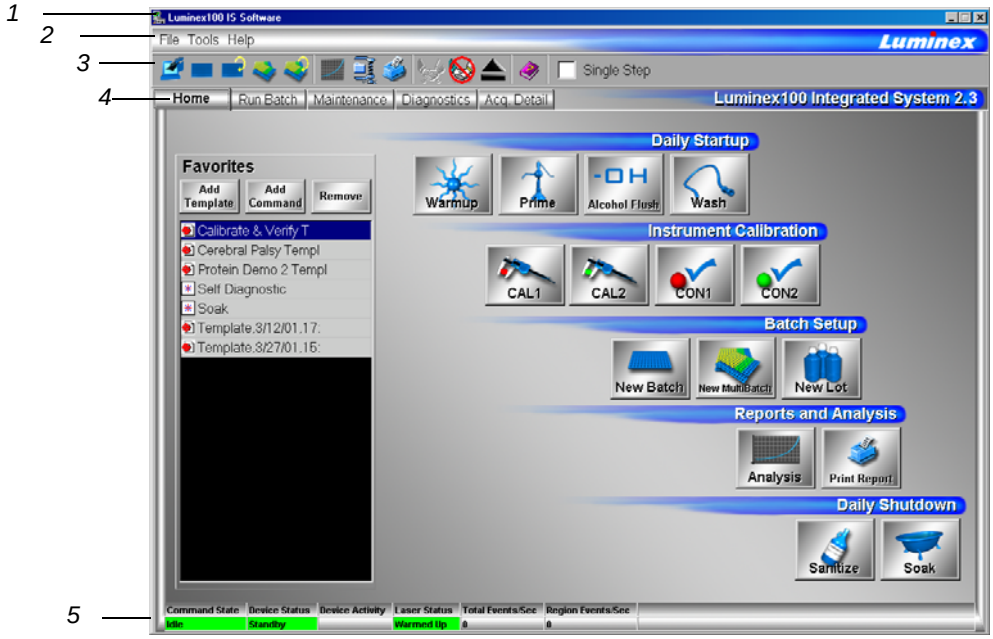
The Luminex 100 IS 2.3 software starts automatically when you log into Windows.

When the Luminex 100 IS 2.3 software starts, a splash screen displays for about ten seconds. See Figure 5-1.

Figure 5-1 IS 2.3 Software Splash Screen

Luminex 100 IS Main Window

The Luminex 100 IS Main window is shown in Figure 5-2.



1. Title bar
2. Menu bar
3. Tool bar
4. Tabs
5. Status bar

Figure 5-2 Luminex 100 IS Main Window

The Luminex 100 IS Main window includes menus and tools to use the software and monitor acquisition and diagnostic processes. These tools include: menus, a status bar, tabs providing access to specific types of information, commands, and features.

The Luminex 100 IS Main window displays five tabs across the top:

Home Tab—This is the default tab. It is organized by the natural order of system use. That is, Daily Startup, Instrument Calibration, Batch Setup, Reports and Analysis, and Daily Shutdown.

Run Batch Tab—This tab contains a command list displaying batch commands and their status, a microtiter plate image, plate command buttons, and Luminex XYP instrument commands and settings.

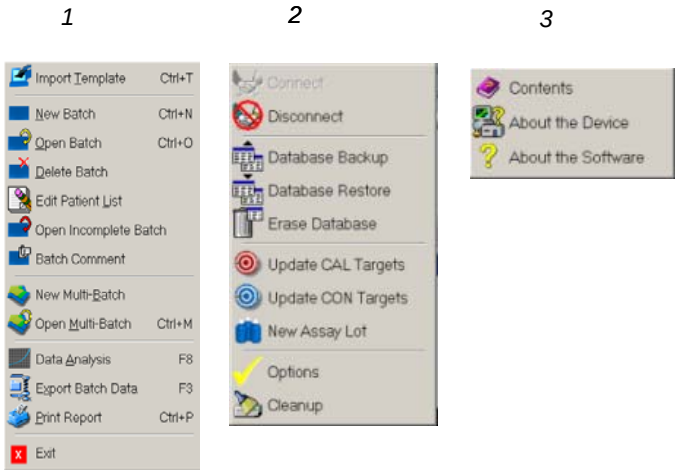
Maintenance Tab—The Maintenance tab contains maintenance commands, XYP commands, and calibration and verification commands for use during system operation.

Diagnostic Tab—The Diagnostics tab displays the progress of commands initiated in the system. The tab also shows specific details regarding each sample analysis and the state of system components. The tab displays the System Monitor, Message Log, detailed sample progress chart, and the status bar.

Acquisition Tab—The Acquisition Detail tab displays the progress of sample acquisition and analysis as the system collects data from the sample. The tab presents the information in different formats, including a session detail table, histogram, and dot plot display.

Menu Bar

The Menu Bar on the Luminex 100 IS Main window has three menus: File, Tools, and Help. See Figure 5-3. Many of the menu items repeat on other toolbars and in dialog boxes. Their use is described throughout the chapter.



1. File Menu *2. Tools Menu* *3. Help Menu*

Figure 5-3 Menu Bar Menus

Options Setup

Set up and customize the system software and enter your company information in the Options dialog box. You can change or update this information as often as you like. The **Software Options** dialog box has three tabs: the General tab, the Company Information tab, and the Data Export tab. See Figure 5-4.

General Tab

You define the following options on the General tab.

Default Batch Directory. Select the default directory where you store batch information. Click the browse button and navigate to the desired folder (directory).

Current User. Enter the name of the current user or operator.

Analysis Display Digits. Use this feature to customize the number of digits shown on the **Data Analysis** dialog box and printed reports. The data is stored with its full precision (that is, including all digits), but the data appears as requested. The default analysis digit display is for two digits to show in the analysis.

Display Confirmation Screens. Select this feature to allow confirmation dialog boxes to display when you initiate many maintenance commands. You can disable the confirmation screen display option so that commands initiated from the Maintenance tab do not display confirmation screens before performing the command. The confirmation screens remain for commands initiated from the Home tab.

Enable Raw Data Storage. Select this feature to save bead event data that is acquired while processing batches in the database. The system defaults to Enable Raw Data Storage. Raw data storage is necessary particularly when you use file mode.

Report Raw Fluorescence. Select this feature to enable the median fluorescence intensity (MFI) display to appear on the Analyte Report. This feature was previously used to display MFI values on all reports. In the Luminex 100 IS software, Version 2.3, the only report affected by this selection is the Analyte Report. All others are hard coded by the system.

Auto-Start Analysis. Select this feature to enable or disable the software to begin analyzing data immediately after processing batches. The automatic analysis feature takes place after the system finishes acquiring data while processing batches.

◆ To configure **General** tab information:

1. On the **Tools** menu, click **Options**, then click the **General** tab.
2. Select the browse button  and navigate to a different folder (directory) if you want the batch files written to a folder other than C:\My Batches (the default location).
3. If desired, enter the name of the current user or operator in the **Current User** box.
4. Enter the number of digits that you want to appear in your sample data in the **Analysis Display Digits** box.

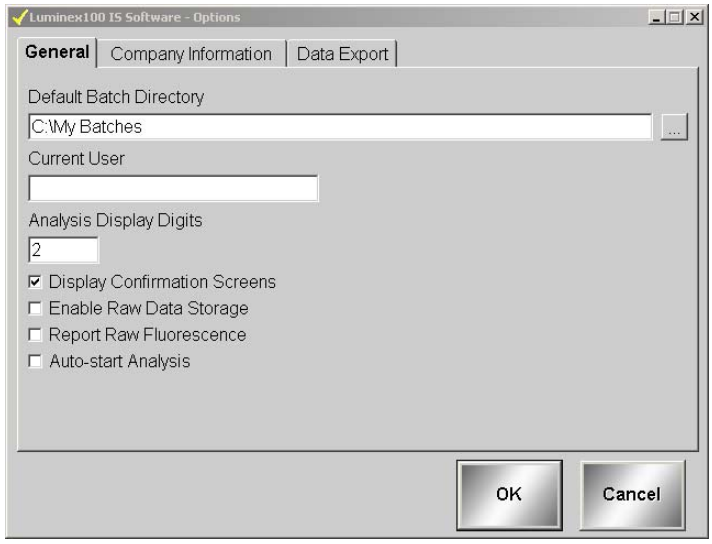


Figure 5-4 Options Dialog Box—General Tab

5. Select the desired checkboxes to enable:
   - Display Confirmation Screens
   - Enable Raw Data Storage
   - Report Raw Fluorescence
   - Auto-start Analysis
6. When satisfied with your selections, click **OK** to save your selections.

Note: You cannot select both Auto-start Analysis and Auto Export Batches (Data Export tab).

Company Information Tab

You can enter information about your company into the **Company Information** tab. This information is stored in the Registry for reference.

◆ To enter your company information into the system:

1. On the **Tools** menu, click **Options**, and then click the **Company Information** tab. See Figure 5-5.
2. Enter your company's name, address, phone, and fax numbers.
3. Enter the location of the company's logo file to use.
4. Click **OK**. The system saves the company information in the database.

Note: For Luminex 100 IS 2.3 software, the logo will not alter any Luminex 100 IS report or screen.

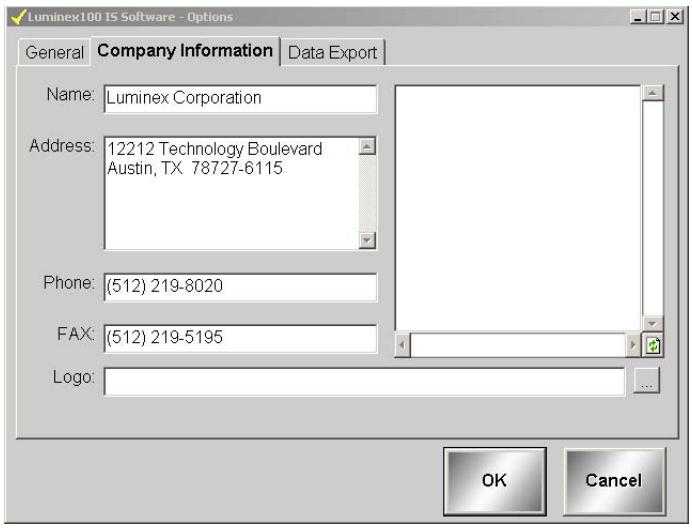


Figure 5-5 Options Dialog Box—Company Information Tab

Data Export Tab

Use this tab to configure your export data. See Figure 5-6. The following checkboxes and radio buttons are available:

Auto Export Batches. Select this feature to automatically export the csv file formats when the system finishes analyzing the batch. This allows you to run your own programs on exported data without having to manually start the export. This feature also takes place after acquisition completes.

Copy Output.csv file to Common Output Dir. Select to send a copy of the Output.csv file to the My Batches/Output folder.

Prompt for Batch Comment. Check this button to initiate a prompt for batch commenting when a batch is finished.

Write Sample Comments. Select to add sample comments to the Notes column in the output.csv file.

Additional Export Stats. Select to define which sample statistics to export outside the Luminex 100 IS software to the output.csv file.

Test Sort Order. Choose an option to define the sorting order. Click the radio button adjacent to the desired test sorting order.

Additional Batch Information. Select one or more options to add additional information to the exported batch file.

Export Location Label Style. Choose one of these options to define the label data style exported to the Output.csv file. You can select sequential numbering, by plate location, or both (default).

◆ To configure the data that you export to files:

1. On the **Tools** menu, click **Options**, and then click the **Data Export** tab. See Figure 5-6.

2. Click the checkboxes and radio buttons next to the desired features for your export data; click **OK** to save your selections.

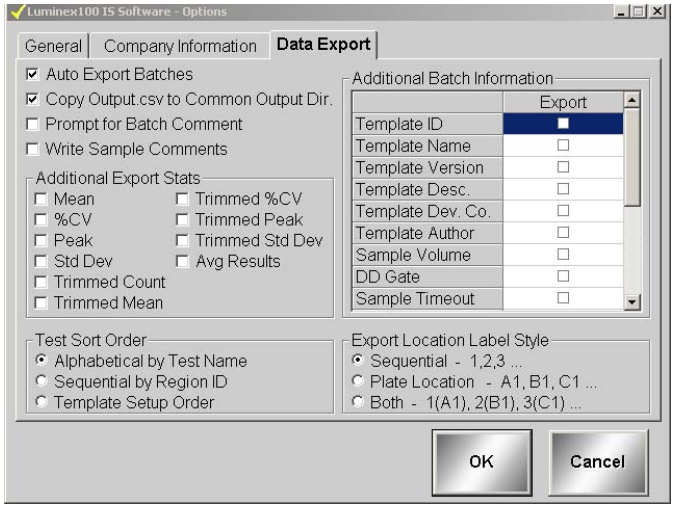
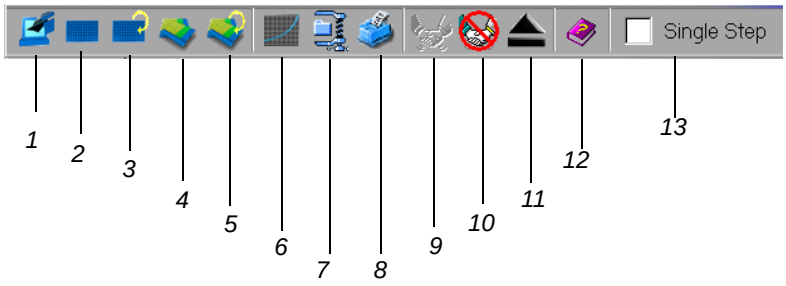


Figure 5-6 Options Dialog Box—Data Export Tab

Toolbar

Figure 5-7 shows the Luminex 100 IS Main window toolbar.



1. Import Templates
2. New Batch
3. Open Batch
4. Create New Multi-Batch
5. Open Multi-Batch
6. Start Analysis
7. Export Batch Data
8. Print Report
9. Connect to the Instrument
10. Disconnect from the Instrument
11. Eject/Retract
12. Open Help Files
13. Single Step

Figure 5-7 Luminex 100 IS System Toolbar

The operation of these toolbar commands is described later in this chapter.

Single Step

Select the **Single Step** option on the toolbar to pause the system in between each command or sample acquisition within a batch. If you enable the single step option, the system pauses between every command or acquisition until you disable (or deselect) the single step option.

Status Bar

The status bar appears along the bottom of the 100 IS Main window and displays the system status. Check the status bar periodically while running a batch to ensure that the system is performing accurately. See Figure 5-8.

Figure 5-8 System Status Bar

The system displays information about the Command State, Device Status, Device Activity, Laser Status, Total Events per Second, and Region Events per Second. Color coding indicates the urgency of each item's status. Device Activity uses no color coding.

Table 5-1 describes the types of status bar messages in relation to the message color coding.

Table 5-1. Status Bar Color Coding

Category	Color	Indicates
Command State	Indicates communication with the Luminex 100 analyzer or operations being processed	
	Green	Idle or processing
	Yellow	Connecting, pausing, or paused
	Red	Disconnected or locked out
Device Status	Indicates the current process of or warning about the Luminex 100 analyzer	
	Green	Running or standby
	Yellow	Busy, pressurizing, sheath is empty, or warming up
	Red	Not ready or disconnected
Device Activity	Indicates the activity that the Luminex 100 analyzer is performing. Note: The device activity has no color code.	

Table 5-1. Status Bar Color Coding (Continued)

Category	Color	Indicates
		• Idling: waiting for a command • Aspirating: drawing in sample • Collecting Data: collecting data • Sanitizing: sanitizing the instrument • Washing: washing the instrument • Priming: priming the instrument • Calibrating: calibrating the instrument • Canceling: canceling a command • Backflushing: backflushing the instrument • Draining: draining the instrument • Warming Up: warming up the instrument • Verifying: verifying calibration • Soaking: soaking the probe • Adjusting sample probe • Self Diagnosing: performing self-diagnostic routine
Laser Status	Laser temperature and readiness status	
	Green	Lasers warmed up
	Yellow	Warmup timer countdown in seconds from 1800
	Red	Lasers off
Total Events/ Second	Number of total bead events detected per second	
Region Events/ Second	Number of bead events detected per second that are classified in a region	

The Status Bar displays status information as the software processes commands. Errors appear in the Message Log at the bottom of the Diagnostics tab.

Text on the Diagnostics tab turns red if the system encounters an error. The Message Log on the Diagnostics tab indicates where the error occurred.

Status Communication Messages

Table 5-2 shows the details of typical messages that appear in the status bar.

Table 5-2. Status Bar Communication Message Details

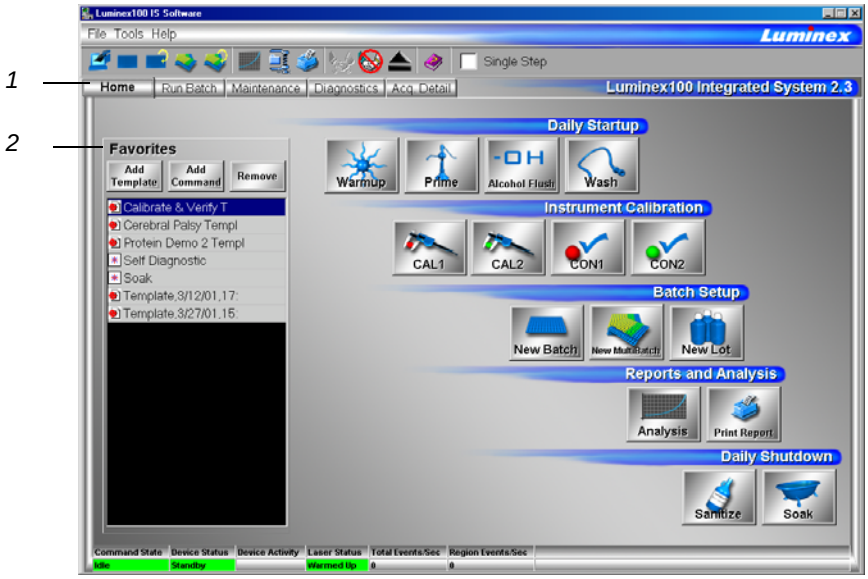
Status Bar Color	Message	Indicates
Green	Idle	Appears when the software is waiting to process the next command.
	Standby	Appears when the Luminex 100 analyzer is ready and waiting to perform a command.
Yellow	Connecting	Appears when the software attempts to connect to the instrument.
	Processing	Appears when instrument communicates with the software as it processes commands.
	Pausing	Appears when the software tells the instrument to stop processing the list of commands and the instrument finishes up the active command.
	Paused	Appears when the software stops processing the list of commands. A “resume” function becomes available to change the state back to “processing.”
	Busy	Appears when the instrument is processing a maintenance command.
Red	Disconnected	Appears when the software has not yet attempted to connect or fails to connect to the instrument.
	Locked Out	Appears when another application currently has control of the instrument. The software locks out as long as the other application runs. To remove the locked out status, close the other application or wait until the application completes.

Tabs

The main window contains five tabs: Home, Run Batch, Maintenance, Diagnostics, and Acquisition Detail. These tabs contain features and commands performed during various stages of the sample acquisition process. Each tab is described in the following sections.

Home Tab

The Home tab is part of the main window. It contains a Favorites list and five categories representing different data acquisition phases, including daily startup, instrument calibration, batch setup, reports and analysis, and daily shutdown. See Figure 5-9.



1. Home Tab button *2. Favorites Section*

Figure 5-9 Home Tab

Favorites List

The Favorites list contains a list where you can add frequently-used templates and commands for easy access. You can tailor the list to your specific needs. For instance, if you use a template often, you may want to include this template in the list. Items appear in alphabetical order for easy locating. See Figure 5-10.

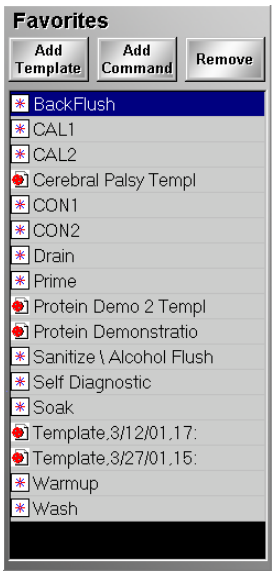


Figure 5-10 Favorites List

Add Templates to Favorites

- To add templates to the Favorites list:

1. On the Favorites list, click **Add Template**.
2. In the **Open Template** dialog box, double-click the template to add to your Favorites list.

Add Commands to Favorites

- To add commands to the Favorites list:

1. Click **Add Command** from the Favorites list. The **Command List** dialog box opens See Figure 5-11.

Figure 5-11 Command List Dialog Box

2. Select the command that you want to add to your Favorites list.

Note: Ensure that the location you select is compatible with the volume intended for that location. The location's capacity may vary depending on the microtiter plate sizes used. Refer to the specifications in Chapter 3 for additional information.

3. For certain commands, select the location where you want to draw or expel fluid. You do this using the location drop-down arrow and clicking over the microtiter plate location on the image. See Figure 5-12. The rectangular box in the upper right corner represents the reservoir.

4. Click **OK** to add the command. The command is displayed in the Favorites List.

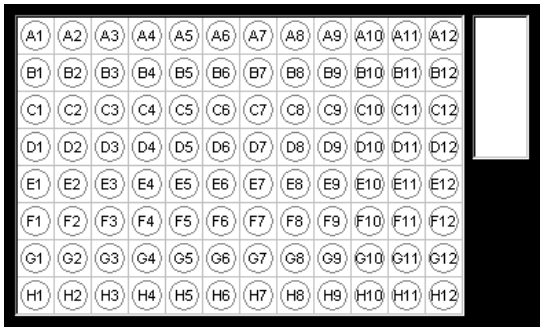


Figure 5-12 Microtiter Plate Image

Remove Items From Favorites

- To remove items from the Favorites list:

  Select the item you want to remove from the Favorites list, then click **Remove**. The item disappears from the Favorites list.

Data Acquisition Categories

The Home tab contains categories representing different phases of data acquisition. Each category consists of a group of command buttons associated with typical phases of data acquisition. At the click of a button, the system performs or initiates the process to perform the function for the button you click. See Figure 5-9.

At the **Daily Startup** section you perform the recommended daily startup procedure by selecting the buttons in the order they appear. These buttons include Warmup, Prime, Alcohol Flush, and Wash. See "Maintenance Commands" on page 5-19 for more detailed information regarding startup functions.

At the **Instrument Calibration** section you perform system calibration and control functions. This section contains CAL1, CAL2, CON1, and CON2 buttons.

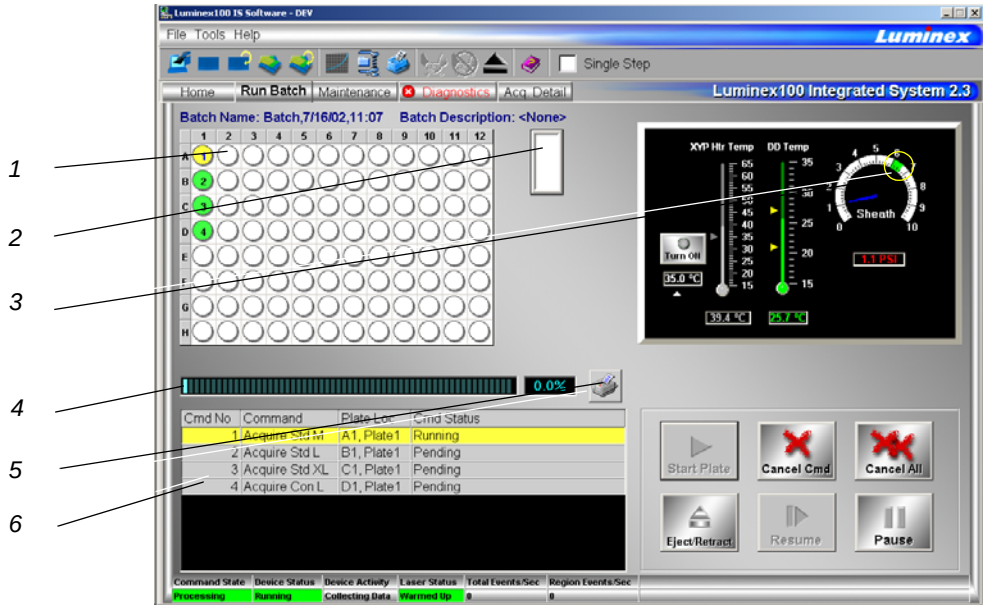
At the **Batch Setup** section you create a new batch, create a new multi-batch, and create new lots for an assay's standards and controls.

At the **Reports and Analysis** section, analyze acquired batch data, compile the data into reports, and print reports from this analysis.

The **Daily Shutdown** section consists of two operations typically recommended during daily shutdown procedures. This section lets you sanitize and soak the system. We recommend that you sanitize with 10% to 20% bleach, wash twice with distilled water, and then soak with distilled water.

Run Batch Tab

The Run Batch tab contains a command list displaying batch commands and their status, a microtiter plate image, plate command buttons, and XYP command buttons and settings. See Figure 5-13.



1. *Microtiter Plate Image*
2. *XYP Reservoir*
3. *Pressure Range*
4. *Progress (when running)*
5. *Print Batch Worklist Button*
6. *Command List*

Figure 5-13 Run Batch Tab

Run Batch Tab Buttons

There are six buttons on the Run Batch tab. These commands are also available on the Acquisition Detail toolbar.

Start Plate Click to initiate data acquisition on new advanced and batches set up using system templates.

Cancel Command Click to cancel the process for the last command initiated.

Cancel All Click to cancel all the commands in process. It essentially performs an abort operation.

Eject/Retract If retracted, click to direct the Luminex XYP to eject the microtiter plate. If ejected, select to direct the Luminex XYP to retract the microtiter plate.

Pause Click to pause or interrupt the command that the system is currently processing.

Resume Click to resume or continue the process that was paused.

Microtiter Plate

The Run Batch tab shows an image representing the microtiter plate where you place the samples. The system analyzes microtiter plate samples in the following order: vertically, from top-to-bottom within the column and left-to-right after each column. See Figure 5-14.

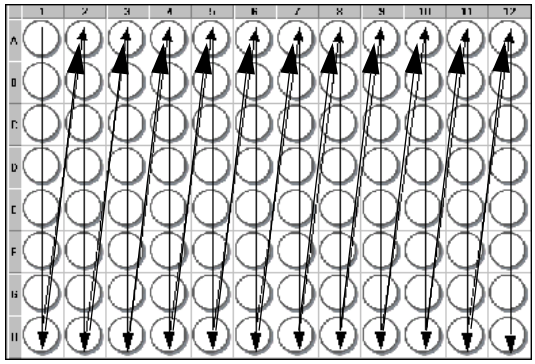


Figure 5-14 Microtiter Plate Image

Luminex XYP Instrument Reservoir

The removable Luminex XYP instrument reservoir (4 mL) holds the fluids used in system maintenance operations, such as washing, draining, or sanitizing. The Luminex XYP instrument reservoir is located at the top right of the Luminex XYP instrument plate holder. The vertical rectangle to the right of the microtiter plate represents the Luminex XYP instrument reservoir on the Run Batch tab. See Figure 5-13.

Temperature and Pressure Gauges

Proper temperature and sheath pressure are essential for optimal system performance. These must be stable before you calibrate and verify the system. The system performs temperature compensation on all samples.

The XYP heater temperature measures the internal Luminex XYP instrument plate temperature.

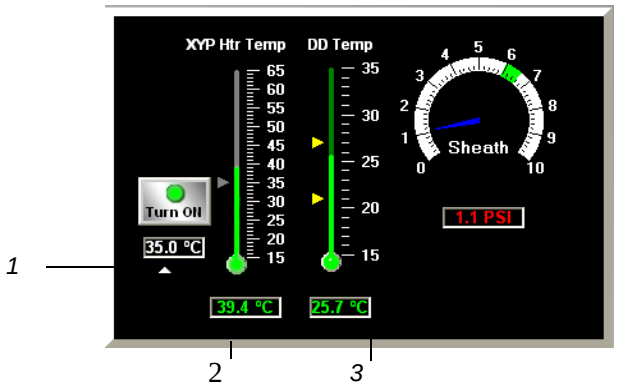
The DD temperature measures the doublet discriminator temperature. DD temperature shifting usually indicates a need for system recalibration. If you see that your DD temperature is out of range

Note: If you have not calibrated, the arrows showing the temperature range for the DD Temperature thermometer both appear at the bottom of the thermometer, and the thermometer appears in red.

(indicated when the DD Temperature thermometer representation turns red), recalibrate the instrument. An out of range temperature logs an error, but does not halt the acquisition.

Refer to Figure 5-13 and Figure 5-15 to identify the temperature and sheath pressure gauges.

Note: While warming the Luminex XYP instrument heater block, the temperature can fluctuate prior to reaching the target temperature. Wait for the temperature to stabilize before acquiring sample.



1. XYP Target Temperature
2. XYP Current Temperature
3. DD Current Temperature
4. Current Sheath Pressure

Figure 5-15 Temperature and Pressure Gauges

Set Luminex XYP Instrument Heater Temperature

Refer to your assay kit instructions to see if the assay needs to be analyzed at a particular temperature. If the instructions indicate that the Luminex XYP instrument heater is needed, you may manually set the heater to the specified heat setting. The user definable heater range is 35°C to 60°C. Use the heater only with the Luminex XYP instrument heater block in place.

Note: Do not use standard 96-well microtiter plates if you are using the heater block.

Luminex recommends using a Costar® Thermowell® thin-wall polycarbonate 96-well plate (nonskirted), model P over the heater block sent with the 100 IS.

Any temperature that you set remains in effect until you set another temperature or turn off the Luminex XYP instrument plate heater.

The system displays the target temperature in the box below the Turn ON button. Before the heater block temperature reaches the new temperature setting, the XYP Heater Temperature thermometer appears red. Upon reaching the target temperature, the thermometer turns green. See “System Monitor” on page 5-37 for more information about the system monitor.

Prior to being turned on or set, the **Turn ON** button appears gray and disabled.

◆ To set the Luminex XYP instrument heater temperature:

Warning: The heater plate of the Luminex XYP instrument is hot when in use and may cause personal injury. Do not touch the heater plate.

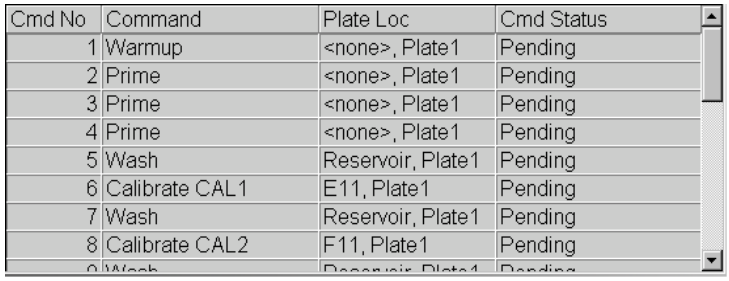
1. Click **Eject/Retract** to eject the plate holder.
2. Insert the Luminex XYP instrument heater block into the plate holder.
3. Click **Eject/Retract** to retract the plate holder.
4. In the **Temperature and Gauges** area, click **Turn ON**. The light on the button turns green and the thermometer fluid turns red as it raises to reach the target temperature.
5. Use the up and down arrows beneath the target temperature box or click and drag the blue arrow on the XYP Heater Temperature thermometer to the temperature you want the Luminex XYP instrument heater block to maintain. The user definable heater range is 35°C to 60°C.

Note: Do not insert a cold heater block into the XYP if the XYP is already warmed up.

6. Wait for the heater to reach your selected temperature and stabilize (about 30 minutes), before processing samples. The thermometer turns green when the temperature is stabilized.

Command List

The Command List displays commands that are associated with batches or multi-batches that you have loaded for processing on the system. The Command List provides the status of each command as the system begins processing it. For example, the command list will show Wash under Command and under Cmd Status that the system is processing the command by displaying Running. The command list indicates whether the command completes successfully or fails. Figure 5-16 shows that all the commands are pending.



Cmd No	Command	Plate Loc	Cmd Status
1	Warmup	<none>, Plate1	Pending
2	Prime	<none>, Plate1	Pending
3	Prime	<none>, Plate1	Pending
4	Prime	<none>, Plate1	Pending
5	Wash	Reservoir, Plate1	Pending
6	Calibrate CAL1	E11, Plate1	Pending
7	Wash	Reservoir, Plate1	Pending
8	Calibrate CAL2	F11, Plate1	Pending

Figure 5-16 Command List Section on the Run Batch Tab

Figure 5-17 shows an example of a failed command in the command list on the Run Batch tab.

1	CON1	C1, Plate1	FAILED (45 sec)

Figure 5-17 Command Failure Notation In Command List

If an error occurs during the batch, it is recorded in the Message Log. See “Error Messages” on page 5-41 for details. Double-click the failure row for additional information if it is highlighted in yellow.

Right-click the highlighted row to copy data to the clipboard or to clear the batch from the screen. Click the **Print Batch Worklist** option, above the upper-right corner, to print the list of commands from the command list. This applies to the current loaded batch.

Print Batch Worklist Button

Click this button to print out the status of each command.

Maintenance Tab

In the Maintenance tab you perform maintenance commands, XYP commands, and calibration and verification commands during system use. See Figure 5-18.

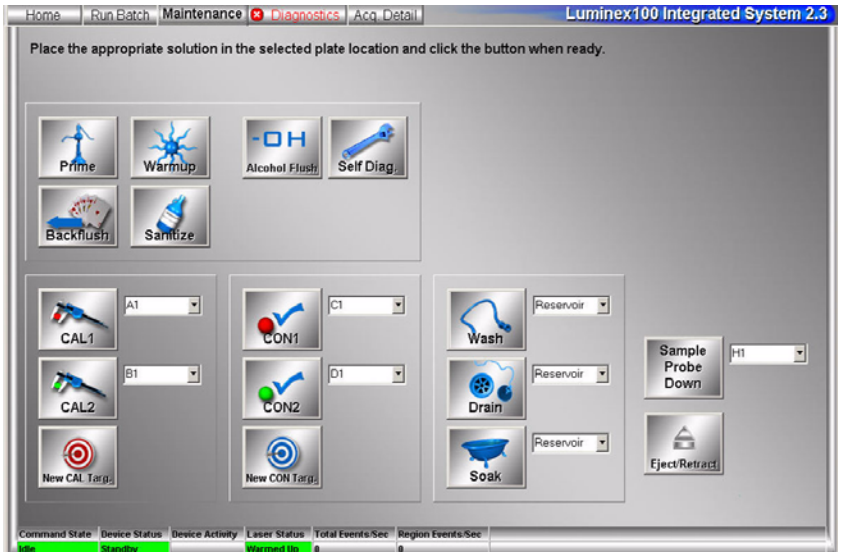


Figure 5-18 Maintenance Tab

Maintenance Commands

Perform these commands to maintain your system and to keep it in optimal working condition. Follow the step-by-step instructions for each command (found after this section) when using as-needed maintenance operations. Some of the commands are also available on the Home tab. The available commands are:

- Warmup
- Prime
- Backflush
- Alcohol Flush - must use the Luminex XYP reservoir due to volume requirement
- Sanitize - must use the Luminex XYP reservoir due to volume requirement
- Wash
- Drain
- Soak
- Self Diagnostics

Note: The Sanitize command performs a similar function as the alcohol flush command. However, the sanitize command uses 10% to 20% household bleach to decontaminate sample lines and the cuvette after biohazard contact.

When the system processes a command that you select from the Maintenance tab, an animated gear graphic appears for a short time in the upper-right corner of the Maintenance tab. The system labels

the command process in yellow text below the graphic. For example, Figure 5-19 shows the Warmup command graphic.

Figure 5-19 Processing Device Activity Commands

Table 5-3 shows a recommended schedule for maintenance operations.

Table 5-3. Maintenance Operations: Recommended Use Schedule

Operation	Recommended Use Schedule
Warmup	• Daily • After four hours of system inactivity
Prime	• Daily • To remove air from sheath fluid tubing • After performing these actions: – refilling the sheath container – removing and replacing sheath container – changing the sheath fluid filter – changing the syringe seal
Backflush	• Troubleshooting purposes only: – to remove obstructions from the cuvette – if fluid does not flow through the waste tubing during prime cycles or during sample acquisition – if fluid drips from the sample probe during priming and forms puddles of fluid on the plate
Alcohol Flush	• Daily • After changing the sample probe • To remove air bubbles from the cuvette using 70% isopropanol or 70% ethanol
Sanitize	• To decontaminate sample lines and cuvette after biohazard contact using 10% to 20% household bleach – daily if working with biohazards – monthly if not working with biohazards

Table 5-3. Maintenance Operations: Recommended Use Schedule (Continued)

Operation	Recommended Use Schedule
Wash	• As needed using distilled water or sheath fluid • Four times after system calibration • Twice after sanitize
Drain	• For troubleshooting only: – the cuvette in the system can be drained temporarily and refilled in preparation for running. Draining the system helps to remove debris from the bottom of the cuvette. – when draining, you do not need to supply solution. Draining takes approximately two minutes and should be followed by an alcohol flush using 70% isopropanol or 70% ethanol.
Soak	• Daily, at the end of the day for shutdown • To prevent salt crystals from forming in the probe due to exposure to air. Soaking the probe replaces sheath fluid in the probe with water. The system uses at least 250 µL of distilled water.
Self Diagnostics	• To see if the device and all system operations are running correctly

If an error occurs, the Diagnostics tab appears in red and the command row containing the error is highlighted. You can double-click that row to see a detailed description of the error.

Warmup Command

Warm up the system to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn power on. This process takes approximately thirty minutes (seconds left appear in status bar). Wait until warmup completes before processing samples.

Caution: Failure to properly warm up the system will effect assay results and system performance.

After four hours of inactivity, the status bar appears red and indicates that the lasers are off. You need to warm up the system again by manually initiating warmup procedures.

◆ To warm up the system:

Click **Warmup**, then click **OK**.

The command list on the Run Batch tab indicates that the system lasers are running. The Device Activity box on the Status Bar indicates that the system is warming. The Laser Status section on the Status Bar is yellow as it counts down from 1800 seconds. Upon completion, the Laser Status bar turns green and displays Warmed Up.

An animated gear appears in the upper-right corner of the Maintenance tab screen.

Prime Command

Prime the system as necessary to remove air from the system's fluidic pathways after:

- refilling the sheath container
- removing and replacing the sheath container
- changing the sheath fluid filter
- changing the syringe seal

You should also Prime your system as part of the daily startup routine.

When priming, the system draws sheath fluid from the sheath fluid container. You do not need to supply solution in a plate. Priming takes approximately one minute.

◆ To prime the system:

Click **Prime**, then click **OK** to confirm that you want to prime the system.

The command list on the Run Batch tab indicates that the system is running. The Device Activity box on the Status Bar indicates that the system is priming. Upon completion, the command list indicates whether the command succeeded with green text or the command failed with red text.

Backflush Command

Backflush the system to perform these tasks:

- to remove obstructions from the cuvette
- if fluid does not flow through the waste tubing during prime cycles or during sample acquisition
- if fluid drips from the sample probe during priming and forms puddles of fluid on the plate

During a backflush, the system draws sheath fluid from the sheath fluid container. You do not need to supply solution in a plate. A backflush takes about seven seconds.

◆ To backflush obstructions from the cuvette:

Click **Backflush**, then click **OK** to verify that you want to backflush the system.

The command list indicates that the system is running. The Device Activity box on the Status Bar indicates that the system is backflushing. Upon completion, the command list indicates whether the command succeeded with green text or the command failed with red text.

Alcohol Flush Command

Alcohol flush the system to remove air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The cuvette is the principal fluid pathway within the optics component of the system where the system reads the sample. The alcohol flush takes about five minutes.

Note: You need to remove air bubbles from the system because air bubbles can interrupt the sample flow and can distort your bead results.

◆ To remove air bubbles from the sample tubing and cuvette:

1. Click **Alcohol Flush.**
2. Click **Eject/Retract**. The plate holder ejects.
3. Place the solution in the reservoir and click **Eject/Retract** to retract the plate holder.
4. Click **OK**. The command list on the Run Batch tab indicates that the system is running. The Device Activity box on the Status Bar indicates that the system is sanitizing. Upon completion, the command list indicates whether the command succeeded with green text or the command failed with red text.

Sanitize Command

Sanitize the system with 10% to 20% household bleach to decontaminate the sample lines and the cuvette after biohazard contact. Luminex recommends sanitizing as part of your daily shutdown routine after biohazard contact. Sanitizing uses the Luminex XYP reservoir location because only the reservoir can accommodate the amount of fluid necessary to sanitize the instrument.

◆ To sanitize for decontamination:

1. Click **Sanitize**. A confirmation dialog box opens prompting you to place sanitize solution in the reservoir.
2. Click **Eject/Retract**. The plate holder ejects.
3. Place the solution in the reservoir and click **Eject/Retract** to retract the plate holder.
4. Click **OK**. The command list on the Run Batch tab indicates that the system is running. The Device Activity box on the Status Bar indicates that the system is sanitizing. Upon completion, the command list indicates whether the command succeeded with green text or the command failed with red text.

Wash Command

Use the wash cycle as needed. For example, wash four times with distilled water or sheath fluid after calibration. Place at least 200 µL in a microtiter well or fill the Luminex XYP reservoir with the sheath fluid. Washing takes about 30 seconds.

Luminex recommends that you wash after calibration and verification, between batches and multi-batches, after sanitize, and before daily shutdown.

◆ To wash the system:

1. On the **Maintenance** tab, click **Eject/Retract**.
2. Put the wash solution into the reservoir or into a well on a microtiter plate.
3. Click **Wash**. A confirmation dialog box opens.
4. If you put the wash solution somewhere other than the default location, click the down arrow on the far right of the dialog box to select the location of the wash solution. A microtiter plate and reservoir image opens as shown in Figure 5-20. Click on the location in the image.

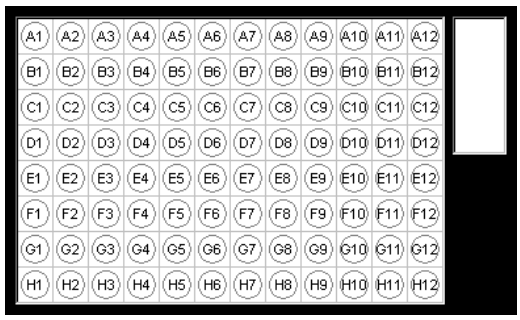


Figure 5-20 Microtiter Plate and Reservoir Image

5. Click **OK**. The command list on the Run Batch tab indicates that the system is running. The Device Activity box on the Status Bar indicates that the system is washing.

6. Wait for the wash to complete. Upon completion, the command list indicates whether the command succeeded with green text or the command failed with red text.

Drain Command

Use the Drain command during troubleshooting to help remove debris from the bottom of the cuvette. Luminex does not recommend routinely draining the cuvette.

When draining, you do not need to supply solution. Draining takes approximately two minutes and should be followed by an alcohol flush with 70% isopropanol or 70% ethanol.

Note: Ensure that the location you select to expel fluid has the reserve capacity to hold the volume expelled.

Any fluid that drains from the system drains to the Luminex XYP reservoir as the default. However, you can set the system to drain to any unused well on the microtiter plate. The drain function normally expels 125 µL of fluid.

◆ To drain the system:

1. On the **Maintenance** tab, click **Drain**. A confirmation dialog box opens.

2. If a different location is desired than what is shown in the dialog box, click the drop-down arrow to the right of the **Eject/Retract** button within the confirmation dialog box. An image of the microtiter plate and Luminex XYP reservoir appears.

3. Select a location on the image of the microtiter plate and reservoir to receive the drain fluid and then click **Eject/Retract**. The plate holder ejects.

4. Verify that the location you indicated is empty and click **Eject/ Retract** to retract the plate holder.

5. Click **OK**. The command list on the Run Batch tab indicates that it is running. The Device Activity box on the Status Bar indicates that the system is draining. Upon completion, the command list indicates whether the command succeeded with green text or the command failed with red text.

Soak Command

Use the Soak command to prevent salt crystals from forming in the probe due to air exposure. Soaking the probe replaces sheath fluid in the probe with water. You should perform the soak function at the end of each day. The system uses at least 250 µL of distilled water.

◆ To soak the probe:

1. On the **Maintenance** tab, click **Eject/Retract**.

2. Put water in the reservoir or into a well on a microtiter plate. Click **Soak**. A confirmation dialog box opens. See Figure 5-21.

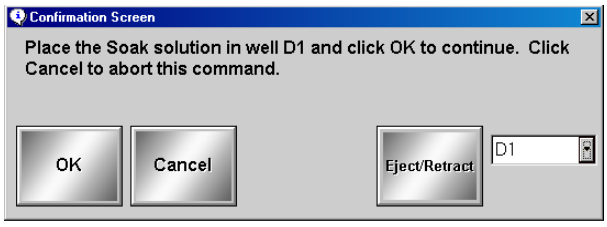


Figure 5-21 Confirmation Screen Dialog Box

3. If you put the water somewhere other than the default location shown in the dialog box, click the drop-down arrow to the right of the **Eject/Retract** button. An image of the microtiter plate and Luminex XYP reservoir appears, shown in Figure 5-22. Click on the location in the image.

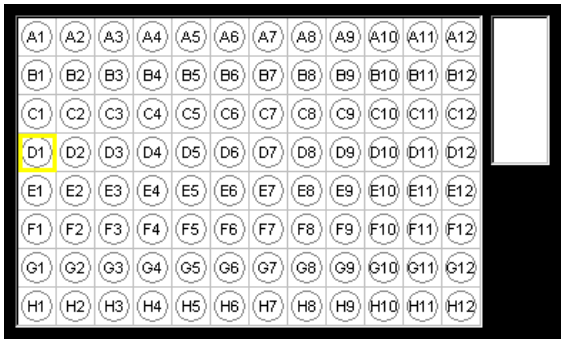


Figure 5-22 Microtiter Plate and XYP Reservoir Image

Note: The system may show a default location. In this case, the microtiter plate shows a well with a yellow line inside the well.

4. Click **OK** . The command list on the Run Batch tab shows that it is running. The Device Activity box on the Status Bar indicates that the system is soaking. Wait until the soak command completes before initiating another command. Upon completion, the command list indicates whether the command succeeded with green text or the command failed with red text.

Self Diagnostics Command

Run self diagnostics to see if the Luminex 100 analyzer and all system operations are running correctly.

Note: Running the self diagnostics test resets the laser and begins a 30-minute warmup process.

The system tests these functions when running self diagnostics:

- Flash memory test
- Microcontroller RAM test
- Nonvolatile memory test
- DSP program CRC test
- DSP capture test
- High voltage module
- Channel backgrounds test
- Pressurization test
- Actuator test
- Syringe pump test
- Backflush valve test
- Debubbler Valve test

◆ To run self diagnostics:

1. On the **Maintenance** tab, click **Self-Diag.**
2. Click **OK**. The system processes the various self- diagnostic tests. When tests are complete, the Status Bar changes from a “Processing” command state to an “Idle” command state. The self-diagnostic tests should take less than one minute to complete.
3. The Command List on the **Run Batch** tab indicates that Self-Diagnostics is running. The Status Bar indicates that the system is self diagnosing. Upon completion, the command list indicates whether the command succeeded with green text or command failed with red text.

If the self diagnosis fails, you can obtain detailed information regarding the results of the self-diagnostic test. See the following "View Self-Diagnostic Details" section.

View Self-Diagnostic Details

◆ To view details of the self-diagnostics test that passed or failed:

1. Click on the **Diagnostics** tab and view the Message log. At least one error from a failed self-diagnostics test appears with a yellow background.
2. Double-click the yellow row to see a detailed description. An **Errors** dialog box opens showing a list of passed and failed self-diagnostic tests. Click **OK** to close this dialog box.

See the Troubleshooting chapter in this manual for additional information about the self-diagnostic failure.

Calibration and Verification

Calibrator xMAP microspheres are used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel. Control xMAP microspheres are used to verify the calibration and optical integrity for the system.

Calibrate the system at least once a month and:

- following installation
- if the system is moved.
- if a part is replaced.
- if the delta calibration temperature shown on the system monitor (on the Diagnostics tab) is more than ±3 degrees.

Each step in the calibration procedure usually takes less than one minute. You must run xMAP controls after each calibration. Once calibrated, the calibration values remain until you calibrate again. You can track system calibration and verification results through the Calibration Trend Report and the System Control Trend report.

You can run calibration and verification commands from the Maintenance tab.

Run System xMAP Calibrators

Note: Lasers must be in the warmed up state to calibrate.

◆ To calibrate your system with xMAP calibrators:

1. Vortex the xMAP calibrators and controls containers to ensure homogeneity.

2. Load a microtiter plate with four to five drops of each: CAL1 in well A1, CAL2 in well B1, CON1 in well C1, CON2 in well D1 and distilled water or sheath fluid in well E1 through H1 to wash a total of four times. Use different wells as necessary. To select different well locations in the software, click on the drop-down arrow next to the entry cell for the calibrator or control, then click in the well location on the microtiter plate image.

3. Click **Eject/Retract**, then place the plate on the plate holder.

4. Fill the Luminex XYP reservoir with a solution of 70% isopropanol or 70% ethanol.

5. Click **Eject/Retract**.

6. On the **Maintenance** tab, click **Prime**. Click **OK** and wait for the Prime to finish (about 1½ minutes).

7. Click **Alcohol Flush**. Click **OK** and wait until the alcohol flush completes. The **Device Status** section in the status bar changes from yellow to green and displays “Standby”. This takes about five minutes.

8. Click **New CAL Targ.** to enter or confirm the calibration lot numbers. The **Update CAL Targets** dialog box opens. See Figure 5-23.

9. Enter the CAL1 lot number.

10. Enter the expiration date. Click the **Expiration Date** box. A “Select Calendar” button appears on the right side of the box.

Click the Select Calendar button to display the calendar.

Type in the date or use the arrows at the top left and right side of the calendar to select past or future months. Alternately, select the month in header. To select the year, click the displayed year in the header. Use the up and down arrows that appear to select a past or future year. Once you select the correct month and year, click the desired expiration day on the calendar. The calendar closes and the new month and year appear in the **Expiration Date** box.

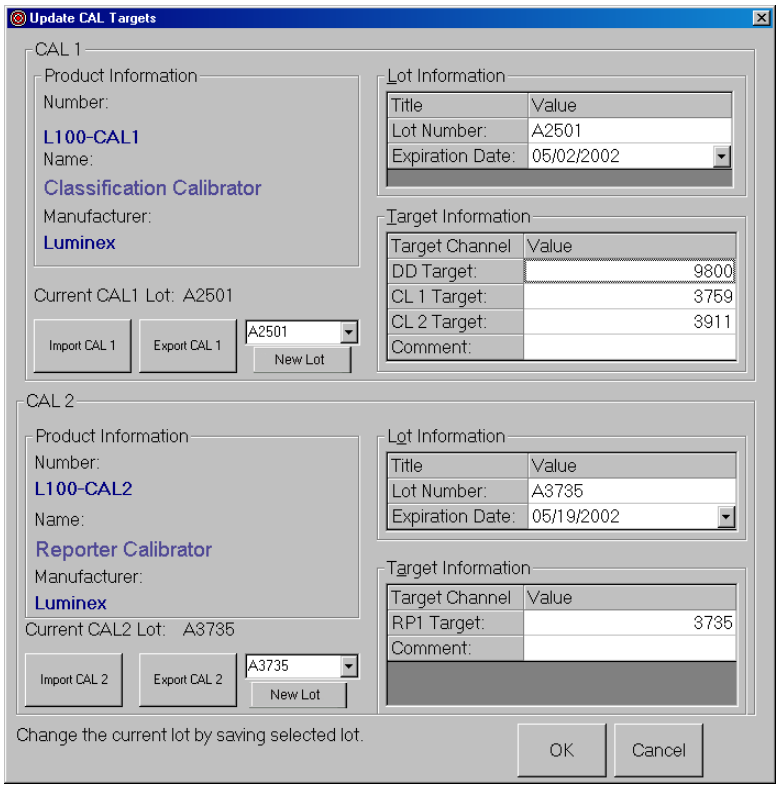


Figure 5-23 Update CAL Targets Dialog Box

Note: Ensure that you enter the correct target values for each parameter before clicking **OK**. You can re-enter any incorrect information.

11. Enter the values listed on the Certificates of Quality (COQ) included with your calibrators into the **CAL1** boxes. You can also find the target value information on the Luminex website at http://luminexcorp.custhelp.com.

12. Enter the CAL2 lot number and expiration date as well as the values listed in the Certificate of Quality, then click **OK**.

13. Ensure that the Luminex 100 analyzer is set to draw the CAL1 and CAL2 beads from the wells you loaded in step 2.

Note: The Diagnostics tab turns red if all substances (CAL or CON) have not been run and under the following conditions:

- the first time the software is opened
- the first time a system is calibrated
- a new database is installed
- an old database is restored
- a CAL or CON fails.

14. In the **Maintenance** tab, click **CAL1,** then click **OK.** The device status section in the status bar changes from “Running” to “Standby”.

15. Click **CAL2**, then click **OK**. Wait until CAL2 completes.

The Device Status section in the status bar changes from “Running” to “Standby” and the Diagnostics tab turns red. The System Monitor on the Diagnostics tab displays the date and time in green if CAL1 and CAL2 are successful.

You must run system controls following calibration. Continue with the following “Run System xMAP Controls” section.

Run System xMAP Controls

To calibrate your system with controls:

1. In the **Maintenance** tab, click **New CON Targ.** The **Update CON Target Information** dialog box opens. See Figure 5-24.
2. Enter the CON1 lot number, expiration date, and the values listed from the Certificate of Quality included with your system controls into the CON1 entry boxes. The target value information is on the Luminex website at http://luminexcorp.custhelp.com.
3. Enter the CON2 lot number, expiration date, and the values listed from the Certificate of Quality, then click **OK**.

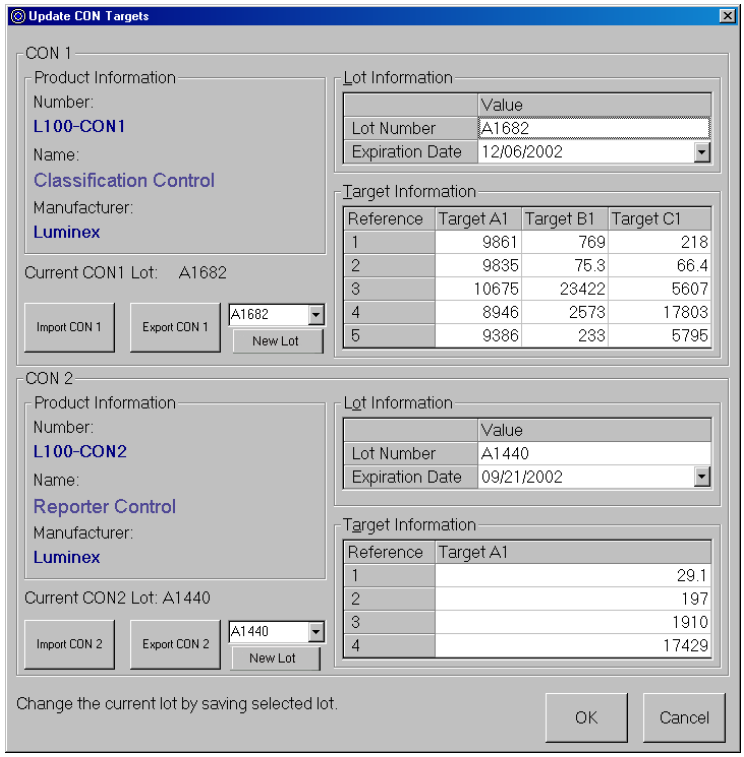


Figure 5-24 Update CON Targets Dialog Box

4. Ensure that the analyzer is set to draw CON1 and CON2 beads from the wells you loaded in step 2 of “Run System xMAP Calibrators” on page 5-28.

5. In the **Maintenance** tab, click **CON1** then click **OK**. Wait until CON1 completes. The Device Status section in the status bar changes from “Running” to “Standby”.

6. Click **CON2**, then click **OK**. Wait until CON2 completes. The Device Status section in the status bar changes from “Running” to “Standby”. The System Monitor on the Diagnostics tab displays date and time in green if both CON1 and CON2 are successful.

7. Ensure the analyzer is set to the draw distilled water or sheath fluid from the well you loaded it in step 2 of “Run System xMAP Calibrators” on page 5-28.

8. Click **Wash** to wash the system after running the system calibrators. Wash a total of four times. You will need to change the well location. Click on the down arrow located to the right of the Wash button.

9. Click **OK** and wait until the wash completes. The device status section in the status bar changes from “Running” to “Standby”.

Note: If an error occurs during system calibration or verification, an **X** appears in front of the Diagnostics tab title, and the text turns red. The command list on the Run Batch tab also reports that the command failed. Figure 5-25 shows the error warnings.

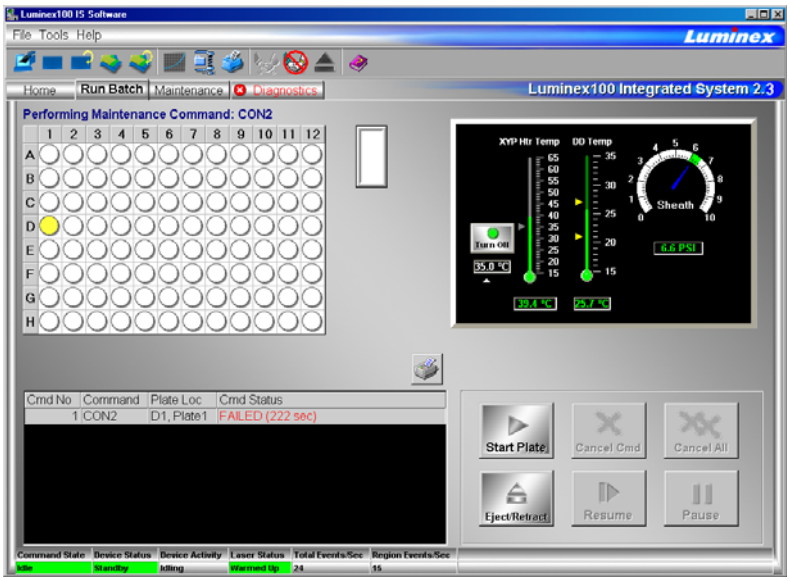


Figure 5-25 Command List and Diagnostics Tab Error Warnings

Calibration and System Control Trend Reports

You can track the results of calibrations and system controls by accessing the Calibration Trend Report or the System Control Trend Report. You can view the expiration date of calibrators and system controls in these reports. These trend reports display a history of calibrations or system controls for a selected date range. You can

print the trend reports. However, you must install the printer on the computer system prior to initiating the print command.

Print or View Calibration or System Control Trend Reports

You must enter information about the date range you want to print a report about.

◆ To create a trend report for a date range:

1. Click **Print Report**. The **Report Selection** dialog box opens. See Figure 5-26.

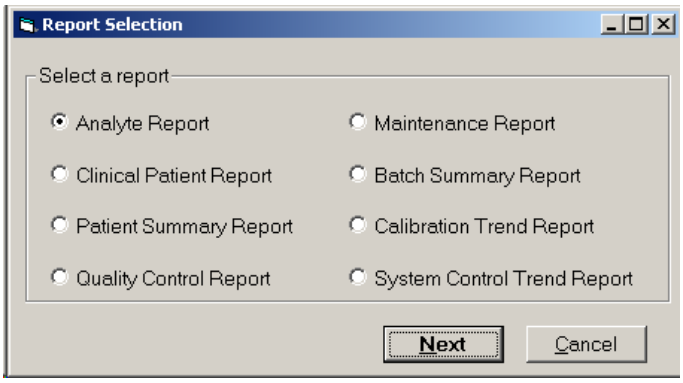


Figure 5-26 Report Selection Dialog Box

2. Select **Calibration Trend Report** or **System Control Trend Report** and click **Next**. The product selection dialog box opens displaying the selected report. See Figure 5-27.

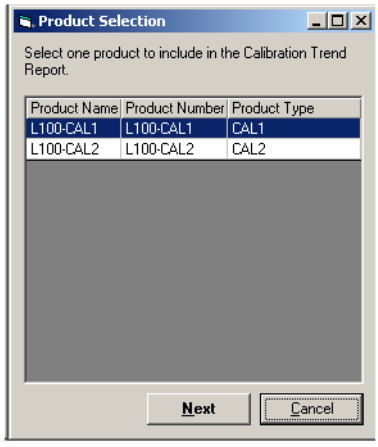


Figure 5-27 Product Selection Dialog Box

3. Select the product for the trend report, then click **Next**. The **Lot and Date Selection** dialog box opens. See Figure 5-28.

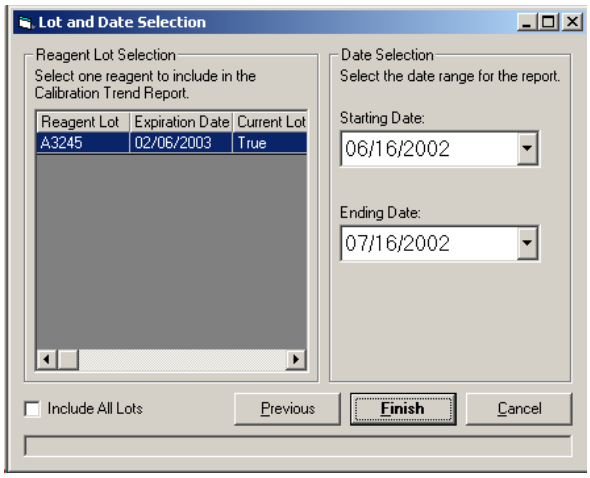
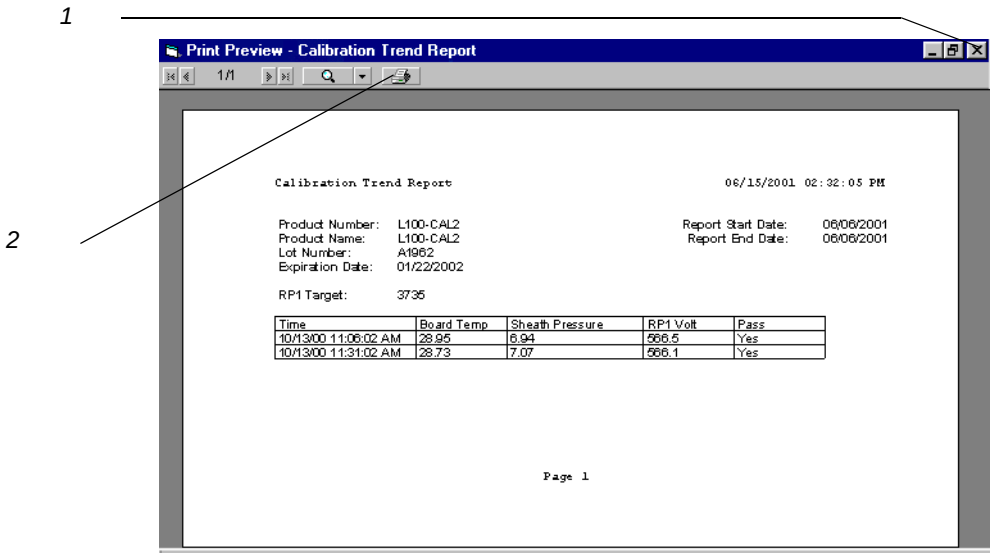


Figure 5-28 Lot and Date Selection Dialog Box

4. Select the desired reagent lot and expiration date, and the date range (starting and ending date) and click **Finish**. **The Print Report - Calibration Trend Repor**t window opens with the information you entered. See Figure 5-29.



1. Click “X” to close screen 2. Print Button

Figure 5-29 Report Print Preview

5. Click **Print**. The **Print Document** dialog box opens. Select the desired options and click **Print**.

6. To close the **Print Preview** window, click the “**X**” in the upper-right corner of the screen. To close the **Report Selection** dialog box click the “**X**” in the upper-right corner or click **Cancel**.

Select Existing Lots for Reuse

You can select existing (previously used) lots for reuse.

◆ To select an existing (previously used) lot:

1. On the **Maintenance** tab, click **New CAL Targ** or **New CON Targ**.
2. Select a lot using the arrows located to the right of the Import and Export buttons in the Update CAL Targets and Update CON Targets dialog boxes.
3. Review the lot information and press **OK** to select the calibration lot.

Import System Calibration or Control Lots

◆ To import system CAL or CON lots:

1. On the **Maintenance** tab, click **New CAL Targets** or **New CON Targets** as appropriate. An **Update CAL Targets** or **Update CON Targets** dialog box opens.
2. Click **Import CAL** or **Import CON** as appropriate. The **Open** dialog box opens.
3. To select the calibration lot or control lot to import, click the drop-down arrow for the **Look in** box. Browse for the appropriate folder, diskette, or CD location.

   After you select the location, the available lots display in the selection list. Click the name of the lot to import and click **Open**. The lot name appears the product information box. The lot and target information is displayed on the Update dialog box.
4. Click **OK** to complete the operation.

Export System Calibration or Control Lots

◆ To export system CAL or CON lots:

1. On the **Maintenance** tab, click **New CAL Targets** or **New CON Targets**. An **Update CAL Targets** or **Update CON Targets** dialog box opens. Ensure you have the desired lot to export displayed or selected.
2. Click **Export CAL** or **Export CON** as appropriate.
3. In the **Save As** dialog box, select the folder (directory) where you want to export the lot as the **Save-in** location. The default is the Backup folder (directory) found in C:\Program Files\Luminex\Luminex 100 IS\Backup.

4. Enter the lot name for the exported lot into the **File Name** box.

5. Click **Save**, then click **OK**. The dialog box closes. After you click OK, you can use the lot target values with the next calibration or verification.

The system saves the lot to the existing software as a lot accessible for the next calibration and/or verification. Once you export the desired calibration or control lot you can save it to disk to import to another computer.

Luminex XYP Instrument Commands

The Luminex XYP instrument commands are those commands primarily involving the Luminex XYP instrument portion of the system.

The Luminex XYP instrument commands let you eject or retract the plate holder on the Luminex XYP instrument and command the sample probe up or down.

Eject and Retract Luminex XYP Instrument Plate Holder

◆ To eject and retract the Luminex XYP instrument plate holder:

1. On the **Maintenance** tab, click **Eject/Retract**. The Luminex XYP instrument plate holder ejects.

2. Click **Eject/Retract**. The Luminex XYP instrument plate holder retracts.

Lower and Raise Sample Probe

Manually raise or lower the sample probe to adjust the probe height. This adjustment is recommended when using different microtiter plates or when changing sample probes. See “Adjust the Sample Probe Vertical Height” on page B-8 for the adjusting procedure.

◆ To lower the sample probe:

1. On the **Maintenance** tab, click the down arrow next to the Sample Probe Down button to select a well location.

2. Click **Sample Probe Down**. Red text appears above the Eject button in the XYP commands section warning you to raise the sample probe after the sample probe adjustment is complete.

3. Click **Sample Probe Up**. The sample probe raises back up to the ready position.

Diagnostics Tab

Use the Diagnostics tab to monitor the progress of commands you initiate within the system. See Figure 5-30. Features on the tab also monitor specific details regarding each sample analysis and the state of system components. The tab displays the System Monitor, Message Log, and Detailed Sample Progress chart.

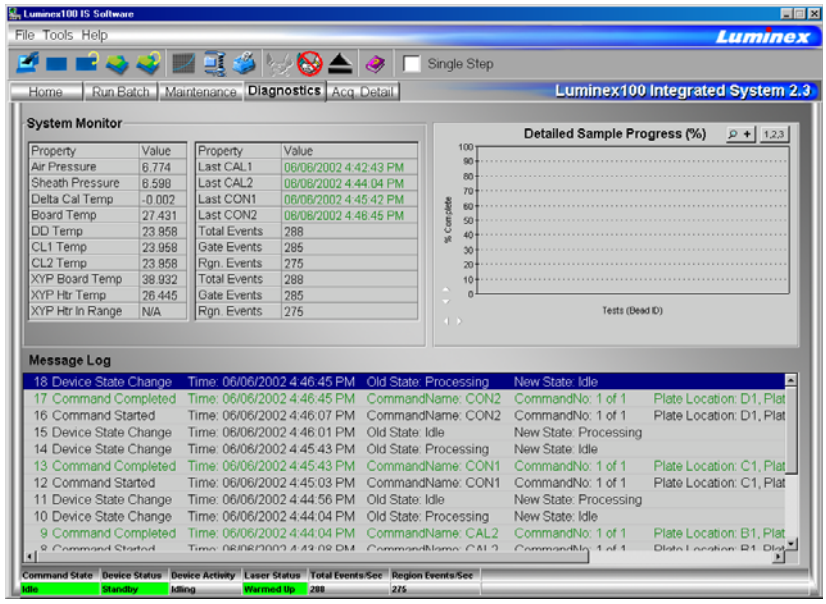


Figure 5-30 Diagnostics Tab

Use these tools to find information about the system and what occurs during sample acquisition and other functions. For example, you may look on the Message Log to see the last completed command or the one currently in progress.

System Monitor

The System Monitor provides information about the physical state of the 100 IS instruments, lasers, and system calibration status.

The values in the System Monitor are reported directly from the Luminex 100 analyzer and the Luminex XYP instrument.

The System Monitor shows whether CAL1, CAL2, CON1, and CON2 results completed successfully by displaying green text for successful events and red text for failed events. See Figure 5-31.

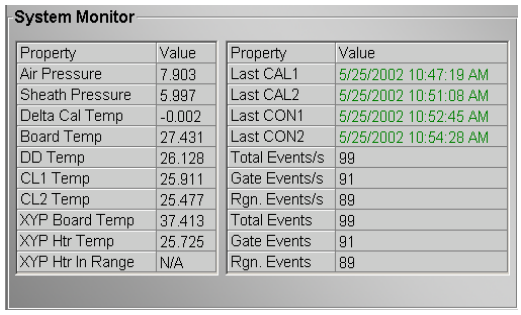


Figure 5-31 The System Monitor

The system can diagnose real-time system problems related to fluid input and output. The system can also detect and report if the Luminex XYP heater block temperature is out of range or unacceptable temperature conditions, including these items:

- Luminex XYP heater block temperature time-out
- heat circuit failure
- temperature out-of-range sensing
- temperature change since calibration, or a change in channel temperature

Table 5-4 defines the values listed in the System Monitor. These values are useful for diagnostic purposes when communicating with Luminex Technical Support.

Table 5-4. System Monitor Values

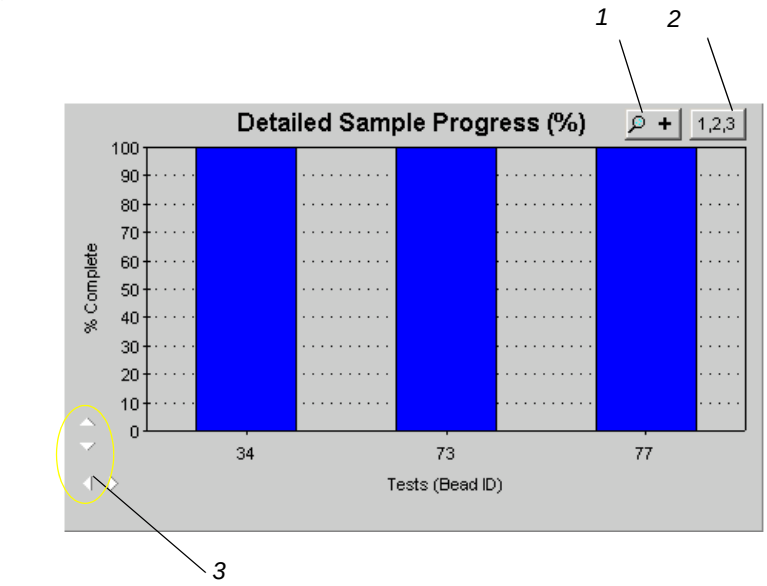
Property	Value Units of Measure
Air Pressure	PSI, air pressure to the sheath container from the air pump
Sheath Pressure	PSI, sheath pressure from the sheath container through the system
Delta Cal Temperature	°C, temperature deviation from the last calibration
Board Temperature	°C, temperature of the analog board
DD Temperature	°C, DD temperature at the U block inside the optics platform
CL1 Temperature	°C, CL1 temperature at the U block inside the optics platform

Table 5-4. System Monitor Values (Continued)

Property	Value Units of Measure
CL2 Temperature	°C, CL2 temperature at the U block inside the optics platform
XYP Board Temperature	°C, temperature of the XYP board inside the Luminex XYP instrument
XYP Heater Temperature	°C, temperature of the XYP heaters inside the Luminex XYP instrument
XYP Heater Temperature In Range	Indicates if the XYP heater is in the set range

Detailed Sample Progress

The Detailed Sample Progress window displays the percentage of completion for each bead ID or test. The graph shows real-time progress, so that as each sample is analyzed, the graph adjusts to show progress. Use the **zoom** button to view up to 20 tests at a time. Use the **toggle** button to view the bead ID or test name. Use the up/down and left/right arrows to expand the chart margins and view longer test names. See Figure 5-32.



1. Zoom button

2. Toggle button

3. Expand Margin arrows

Figure 5-32 Detailed Sample Progress

Message Log

The Message Log shows a list of completed commands, errors, and warnings. It is located on the lower part of the Diagnostics tab. It also displays each operation's progress, time and date, and results. See Figure 5-33.

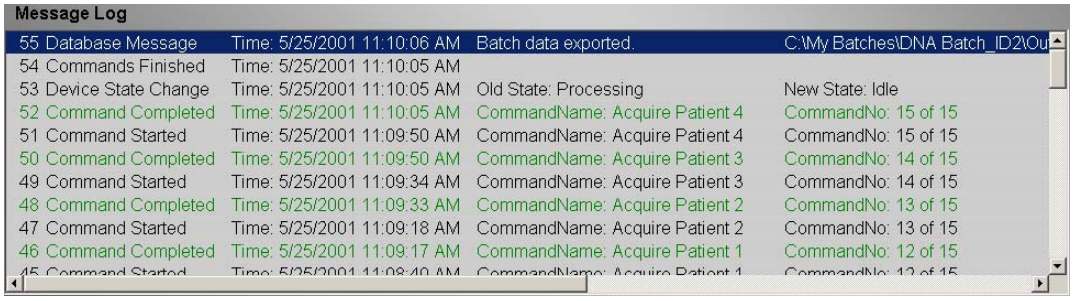


Figure 5-33 Message Log

The log also displays actions in color-coded text and shading. Items in the Message Log appear in the following color codes:

- Green text represents a successful system calibration, verification command, acquisition, or maintenance functions.
- Red text represents failed commands or errors.
- Black text represents normal processes and actions.
- Yellow shading behind the text represents that a detailed description about the processes or actions is available. This color may vary from system to system depending on your tool tip color system settings.

  The color shading appears only when a more detailed explanation exists for the item.

  To see this detailed description, double-click the row that is shaded in yellow. A dialog box opens providing details about that action or process. This function is particularly helpful if you need to diagnose a problem with the system or reagents.

If an error occurs during the batch, it is recorded in the Message Log.

Clear the Message Log

This command clears the Message Log on the Diagnostics tab. It **does not** erase the message log file in the database.

◆ To clear the Message Log:

Right-click in the Message Log. From the menu select **Clear**. Click **Yes** to confirm your selection. See Figure 5-34.

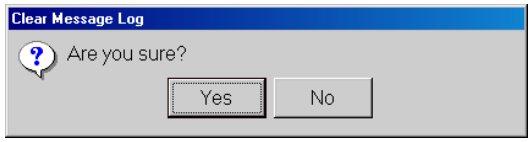


Figure 5-34 Clear Message Log Dialog Box

Error Messages

If an error occurs during system operation the Diagnostic tab turns red. Click on the **Diagnostics** tab. The Message Log displays errors as a row with red text. If the row with the red text has a yellow background, double click that row. An Error message appears with error details.

Acquisition Detail Tab

The Acquisition Detail tab offers advanced batch sampling monitoring and “on the fly” data acquisition without using templates. The primary function is real-time monitoring of batch samples during acquisition through the display of sample bead statistics, histogram, and dot plot data.

During batch acquisition, certain bead statistics can be useful if batch errors occur. For example, if samples are constantly failing due to insufficient bead count, you can monitor whether the failure is due to low sample bead concentration or if other assay problems are present.

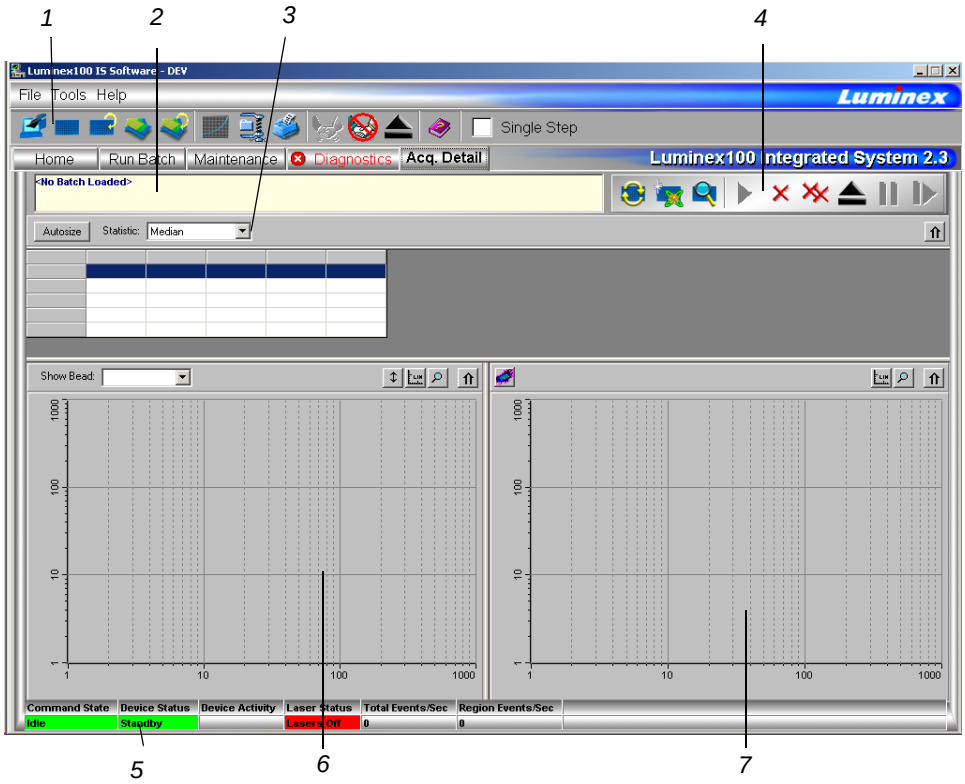
The Acquisition Detail tab provides access to the Luminex 100 IS Developer Workbench (DWB) software features. Details about these features are provided in the *Luminex 100 IS Developer Workbench Guide Version 2.3* documentation. You must have the DWB software installed to enable these features.

Caution: End users should not alter kit manufacturer’s predefined templates or create alternative templates for off the shelf kits unless instructed by the kit manufacturer.

Acquisition Detail tab Main features:

- New Advanced Batch
- View Batch Data
- Replay
- Histogram
- Dot Plot

This section provides an overview and basic descriptions of the Acquisition Detail tab. Figure 5-35 displays the Acquisition Detail tab and identifies the major features.

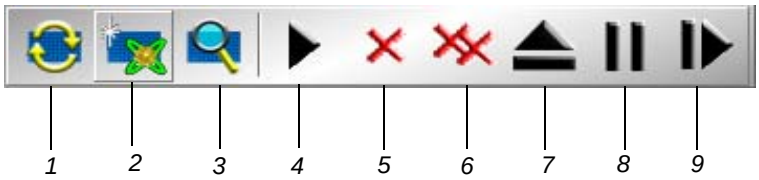


1. *IS toolbar*
2. *Batch name and description*
3. *Batch data area and buttons*
4. *Acquisition detail toolbar*
5. *Status bar*
6. *Histogram*
7. *Dot Plot*

Figure 5-35 Acquisition Detail Tab

Acquisition Detail Toolbar

The Acquisition Detail toolbar provides batch and advanced functions to acquire raw data without using templates. The toolbar provides a variety of commands to use during a batch, including: Start Plate, Cancel Command, Pause, and Resume.



1. *Replay batch*
2. *New advanced batch*
3. *View batch data*
4. *Start*
5. *Cancel*
6. *Cancel All*
7. *Eject*
8. *Pause*
9. *Resume*

Figure 5-36 Acquisition Detail Toolbar

Replay Batch Click to replay batch sample acquisition. All batch commands are replayed allowing for batch acquisition viewing exactly as in real-time. You cannot replay New Advanced Batches. When running a Replay Batch command, the original acquisition data is not altered. A new file is created. the most common use is for system demonstration and training.

New Advanced Batch Assay developers use New Advanced Batch to acquire data without having to build templates. This provides the developer with a faster and convenient tool to develop assays. It does not store the results in the Luminex 100 IS database. It writes raw data to the output.csv file if Auto Export is selected, and writes run files if Enable Raw Storage is selected. This feature is the primary use of the Acquisition Detail tab. When you click on the New Advanced Batch button, the Options tab displays with the following tabs:

General -use this tab to enter general information about the batch.

Bead Set - use this tab to define the bead events for the session.

Plate Layout - use this tab to define commands for desired wells on the plate.

View Batch Data Click to open a previously acquired batch that is stored in the database. You cannot view New Advanced Batches.

Start Click to start data acquisition on the new advanced or selected batch.

Cancel Click to cancel the process for the last command initiated in the system. The system then processes the next command.

Cancel All Click to cancel all the commands in process.

Eject (Retract) Click to eject or retract the microtiter plate on the Luminex XYP.

Pause Click to pause the command that the system is currently processing.

Resume Click to resume or continue the process that was paused.

Batch Data Area and Buttons

This refers to the screen area from the bottom of the toolbars to the top of the Histogram/Dot Plot.

Batch Name and Description The system displays the batch name and description in the upper-left side of the Acquisition Detail tab.

Batch Data Area This displays sample results. The left column shows plate location and well description. The remaining columns display selected bead

sets for the assay. Each row represents the data for each bead set from one well.

Copy and Export Menu

This popup menu is available when you right-click in the Batch Data Area. Select Copy to copy the currently displayed data to the clipboard. Select Export to manually export the currently loaded batch to the appropriate Output.csv file.

Autosize

Click to automatically adjust column widths to fit the data and header sizes.

Statistics

Allows you to display the selected statistics for your sample data. Select an entry from the scroll list. There are eleven statistics:

This does not change the format of the expected data.

%CV	Trimmed %CV
Count	Trimmed Count
Mean	Trimmed Mean
Median*	Trimmed Peak
Peak	Trimmed StdDev
StdDev	

*Luminex 100 IS 2.3 software and Luminex 100 IS Developer Workbench use only median statistics. However, you can export the other statistics to reports. You define which statistics to export through the Data Export tab on the Options dialog box (select Tools Menu, then Options).

- **%CV**—Coefficient of Variation = Standard Deviation/Mean x 100%
- **Count**—Gated events, if gates are set
- **Peak**—Histogram bar with the highest value
- **Std. Deviation**—Standard deviation from the mean. SD Formula:

$$s = \sqrt{\frac{\Sigma(x-\bar{x})^2}{(n-1)}}$$

- **Median**—The middle value in a list of ascending ordered values
- **Mean**—Average of all values in the list
- **Trimmed**—All trimmed statistics remove the lower and upper five percent of the extreme statistic values, then used for the %CV, Count, Mean, Peak, or StdDev.

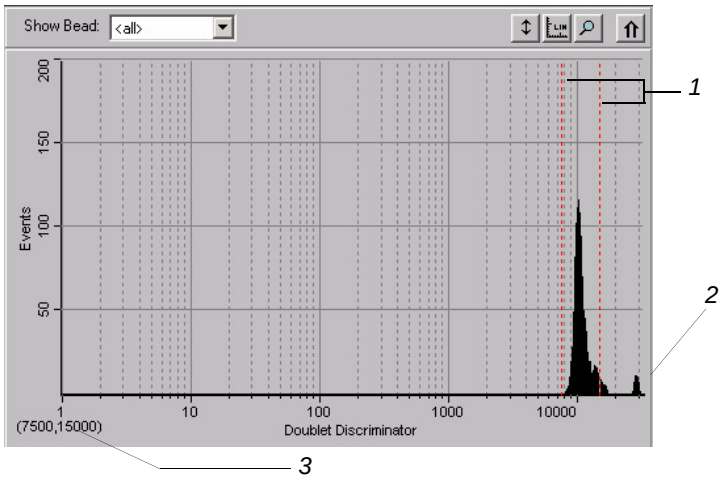
Histogram and Gates

This section provides an overview of the Histogram and Gates. Details are provided in the *Luminex 100 IS Developer Guide for xMAP Technology Version 2.3*.

Note: You cannot change the gate position during batch acquisition. You can change the gate positions before data acquisition, after the system finishes acquiring data, or after pausing the system. However, the change is visual. The data is still collected according to the gate positions set in the assay template or New Advanced Batch set-up.

The histogram appears in the lower-left section of the Acquisition Detail tab. See Figure 5-37. The histogram defaults to display the Doublet Discriminator (DD) on the X axis and Events on the Y axis. Doublets appear when two microspheres stick together, creating undesired results. When you enable the gate, two vertical red, dashed lines appear to represent gate positions determined by the template or settings established within the New Advanced Batch. After setting the gate, everything outside the gate is ignored.

Note: The gate in effect when the system collects data determines which values to use to obtain the result. Applying a gate or changing a gate for existing data does not change your calculated values. The gate positions used while collecting data are the numerical values selected in the template or the New Advanced Batch (also located in the lower corner of the histogram).



1. Gate Boundaries 2. Aggregate Beads 3. Numerical Gate Position

Figure 5-37 Set DD Gate Example

Histogram Buttons

Four buttons and the Show Bead entry box appear at the top of the histogram:

Show Bead

Select an entry from the drop-down list to set the histogram to show events for only one bead set [bead set number], <all gated> events within the gate, or <all> events inside and outside the gate. Select <all> (default) before setting the gate.

Note: The calculated data uses only <all gated> events to determine the final result.

Auto Scale

Select to automatically adjust the maximum number of events shown on the Y axis. Click during acquisition to readjust the Y axis scale.

Zoom

Select to zoom or enlarge a specific area on the histogram display. Click and drag right to left to adjust the graph's range.

Log/Linear Select to toggle the X axis scale between logarithmic and linear modes.

Maximize/ Minimize Select to toggle between maximum and minimum histogram views.

- Click **Maximize** (up arrow) to enlarge the entire histogram and observe in greater details.
- Click **Minimize** (down arrow) to reduce the histogram down to original size.

Dot Plot

This section provides an overview of the Dot Plot. Details are provided in the *Luminex 100 IS Developer Workbench Guide Version 2.3*.

The **Dot Plot** (or bead map) appears in the lower-right section of the Acquisition Detail tab. See Figure 5-38. The dot plot shows a graphical display of real-time data collection as a dot plot. You may define the X axis and Y axis scales from within the dot plot.

Note: You can change the X axis and Y axis of the dot plot for troubleshooting purposes. Luminex recommends using the default settings in all other scenarios.

Luminex recommends using the default settings to collect data. The default axis are Classification 1 on the X axis and Classification 2 on the Y axis. To see the dot plot, you must use the default axis. To display the bead set information, hover the mouse pointer over the desired region and click.

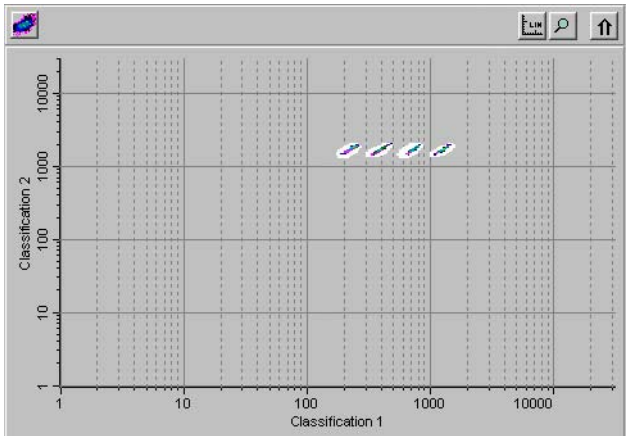


Figure 5-38 Dot Plot Display Example

Dot Plot Buttons Four buttons appear at the top of the frame to control the display:

Density/ Decaying Select to toggle between the default density dot plot and the decaying dot plot views.

The Decaying Dot Plot plots only the 100 most-recent acquired events.

The Density Dot Plot displays a constant accumulation of events. Increasing density is indicated by contrasting colors. See Table 5-5 for the density dot plot color legend.

Table 5-5. Dot Plot Color Legend

Layer	Color
0	none
1	dark blue
2	pink
3	dark green
4	cyan
5	light blue
6	light green
7	orange
8	dark red

The density dot plot allows visual elimination of data values determined to be insignificant to the display.

Luminex recommends you collect your data in density dot plot mode to observe all collected events. Post acquisition does not display decaying dot plot; it's only a real-time function.

Log/Linear Click to toggle the X axis and Y axis scale between logarithmic and linear modes. This button is only active when viewing a dot plot.

Zoom Click to zoom or enlarge a specific area on the display to focus in on any specific area that you want to see in detail. Use the scroll bar to move across the bar graph. Click and drag right to left in the dot plot to navigate around the dot plot.

Maximize/ Minimize Click to toggle between expanding the entire dot plot and returning the dot plot to original size.

Replay Batch (File Mode)

You can reprocess batches through the system multiple times using Replay Batch. Replay Batch uses the data stored in the run files from the initial acquisition to reprocess a batch, creating a new batch output file.

Note: The initial batch data and output file always remain intact and unchanged.

Each time you reprocess a batch using Replay Batch, the system handles it as if it is a new batch; thus, creating a separate processed batch entry and output file.

You reprocess a batch using Replay Batch to:

- Run as demonstrations to see how the system processes samples and analyzes the results.
- Test a batch using different parameters, such as setting a different number of events to be collected or using a different bead map or new formula for analysis, also using a different template.

Note: The number of beads for collection must be less than or equal to the number previously collected in the original sample.

If you reprocess a batch with the same template parameters, the system obtains results similar to the original batch. If you reprocess a batch using changed parameters, the system may obtain different results.

When you replay a batch it labels unknown samples as Pa1, Pa2, Pa3, and so on.

If you replay a batch containing replicates, replicate averaging will not be calculated in data analysis.

A number of variables can affect the final test results. You may also change the standards or controls processed with the batch or multi-batch. These variables may effect your test results:

- minimum number of events for acquisition
- formula used to analyze the MFI values
- standards or controls validation or invalidation
- type of analysis (qualitative, quantitative, acquisition only, or maintenance)

Reprocess Samples Using Replay Batch

Reprocess samples using **Replay Batch**.

◆ To reprocess samples using Replay Batch:

1. On the **Acq. Detail** tab, click **Replay Batch**. The **Browse for Folder** dialog box opens displaying the My Batches folder.
2. Select the desired batch under the **My Batches** folder and click **OK.**
3. The **Open Template** dialog box opens. Click on the desired template and click **Select**.
4. The **Run Batch** tab becomes the active tab. You can monitor the commands as they process. Click on the **Acq. Detail** tab and monitor the data, histogram, and dot plot.

Analyze Reprocessed Data with Replay Batch

After replaying a batch, you can analyze the data.

◆ To analyze Replay Batch data:

1. Click **Start Analysis**.
2. In the **Open Batch** dialog box, select the batch you want to analyze, then click **Select**. The most recent Replay Batch is the last or has the highest ID number. See Figure 5-39.

Note: The Open Batch dialog box does not list or show the templates associated to the batches.

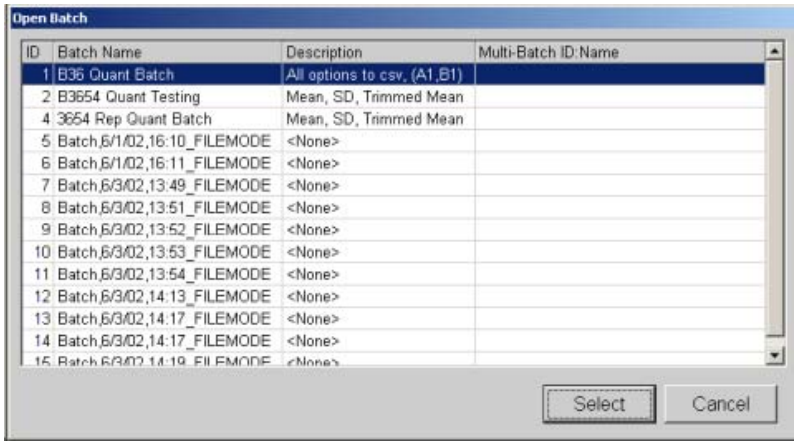


Figure 5-39 Analyze Open Batch

3. The **Analysis** window opens, showing the Batch info in the Standards tab. To close the Analysis window click **Close**. See “Analyze Batches and Multi-Batches” on page 5-85.

Batches

A batch consists of a group of samples processed under control of a template. Batches are set up using templates defined by assay kit manufacturers. Batches consist of templates and samples for acquisition, and can span more than one plate. Templates contain predefined commands that must be included in every batch acquisition. Commands may consist of Acquire Standard, Acquire Control, Acquire Background, Wash from Well, or Prime.

You can group batches together as a multi-batch. Multi-batches can consist of any number of batches that have been setup from different assay templates and are processed consecutively.

The assay kit manufacturer may provide templates in the kits, which they distribute on diskette or CD ROM. Templates typically include assay standards, controls, and maintenance commands (such as

washes or primes to acquire along with samples). OEM manufacturers may provide templates pre-installed with your system.

The kit manufacturer includes assay reagents in the assay kit. You must provide information about these reagents, such as lot numbers and concentration values for the standards and assay controls.

A batch can include samples across more than one plate. When setting up a batch, if the number of samples exceeds the wells in one microtiter plate, another plate appears for additional samples. The new plate appears to the immediate right of the existing plate image on the screen with a dark line between the adjacent columns of the two plates.

During acquisition, the Run Batch tab displays the wells containing the samples in the microtiter plate. Colors indicate the progress in analyzing the samples. The following well colors indicate well-acquisition states:

- Green well: with command number—sample not acquired.
- Yellow well: sample currently in acquisition
- Red well: sample failed. Check the system monitor for more information
- Green background: with check mark—successfully completed

Note: Common sample errors are due to lower number of events acquired than established in the template.

The System Monitor (on Diagnostic tab) also indicates the well acquisition status and highlights the current well in progress.

Batch Commands and Procedures

Create a New Batch

◆ To create a new batch:

1. Read the instructions provided with the assay kit you are using. Follow the instructions for any preparations.
2. On the **Home** tab, click **New Batch**. The **Open Template** dialog box opens. See Figure 5-40.

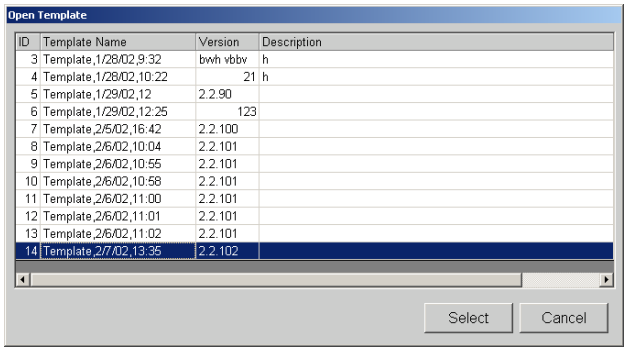


Figure 5-40 Open Template Dialog Box

3. Select the template you want to apply to the new batch and click **Select**. The template loads, and the **Luminex Batch Setup** dialog box opens. See Figure 5-41.

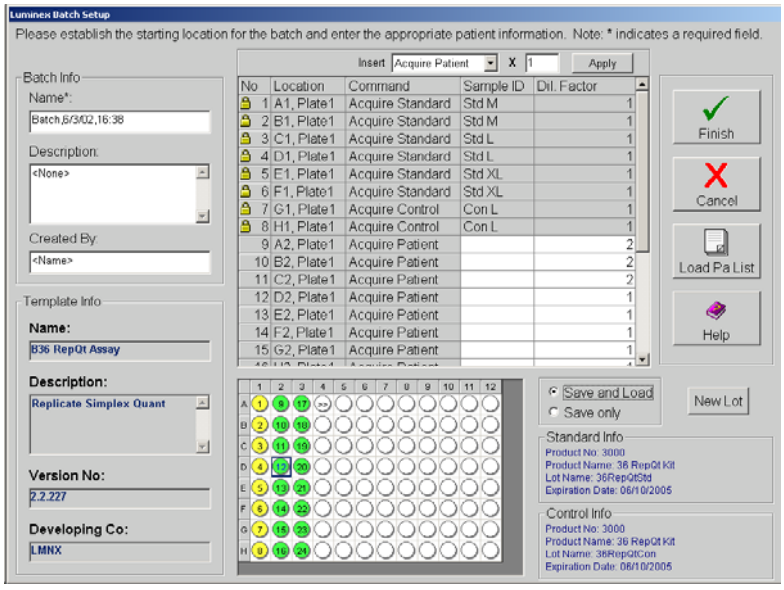


Figure 5-41 Luminex Batch Setup Dialog Box

4. Enter the batch name (if different from the system default name provided), a description (optional), and the creator's name.

5. To add samples for processing in addition to the template commands in the batch that you are creating, scroll down to the last item in the command list section (to the left of the Finish, Cancel, Load Patient List, and Help buttons). If you are running a maintenance template, go to step 11 to save and finish creating the new batch.

6. Click the **Sample ID** box on the last row for the empty well on the microtiter plate. See Figure 5-42.

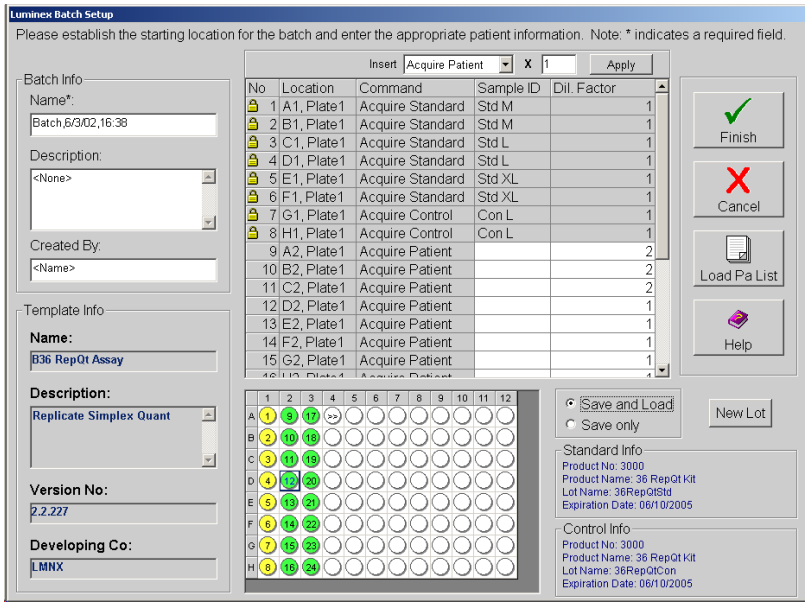


Figure 5-42 Entering Additional Samples

Note: Batches may span more than one plate. When the first plate is full, a blue line appears separating the columns of the first plate with those of a second plate.

7. Enter the sample ID for the sample to add to the batch. Repeat this step to add all of the additional samples to the batch. You can enter the sample manually, through a patient list, or scanned in using the system barcode reader.

8. To add a patient file to the batch, click **Load Patient List**. An **Open Patient List File** dialog box opens. See Figure 5-43. If you do not want to add a patient list to the batch, skip to step 11.

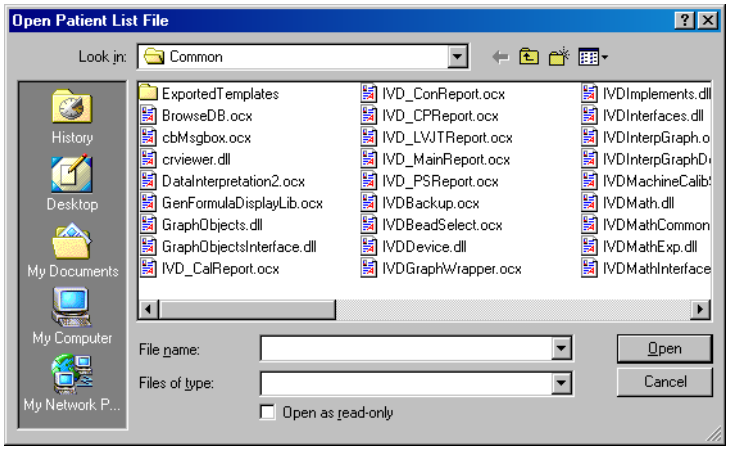


Figure 5-43 Open Patient List File Dialog Box

Note: If any of the acquire sample commands within the template of the batch has an unassigned Sample ID, the system applies the first patient ID in the list to the unassigned sample acquisition command. The system appends any remaining patient IDs to the end of the command list in the order as they appear in the patient list.

9. Select a patient file to append to the batch and click **Open**. The system appends the patients to the batch.

   If all patient IDs in the batch are identified, the system appends the patient list items to the first empty location following the batch's last command list activity. See "Add a Patient List" on page 5-61 for information regarding the patient file format.

10. Ensure that the dilution factor settings are correct for the samples in the batch. If any are incorrect, enter the appropriate dilution factor. See page 5-65 for more information.

11. Select **Save and Load** or **Save Only**.

12. Click **Finish**. If you selected Save and Load, the Run Batch tab opens displaying the batch, including the samples you added. If you selected Save only, the system becomes idle as it waits for you to initiate a command.

13. If you selected Save and Load, load the microtiter plate using the Eject/Retract button, then click **Start Plate** to initiate batch acquisition.

Insert Menu

The Insert menu allows you to add a user-defined number of patients to the command list, or skip a defined number of wells on the microtiter plate. See Figure 5-44.

The Insert menu contains a list box, multiplier box, and Apply button. In the list box you select Acquire Patient or Skip well command.

Note: When you use the Load Patient List feature all the Sample IDs and Dilution Factors are predefined. See "Add a Patient List" on page 5-61 for additional information.

- **Acquire Patient**—Use this command to add patients to the command list. After adding the patients you define the Sample ID and Dilution Factor for each new patient. The Dilution Factor defaults to 1.
- **Skip** [wells]—Use the Skip command to deliberately bypass specific wells during batch acquisition. This may be useful where a certain sample failed.

Figure 5-44 Insert Menu Section

◆ To insert the Acquire Patient or Skip command:

1. On the **Home** tab, click **New Batch**.

2. In the **Open Template** dialog box, select the desired template.
3. The **Luminex Batch Setup** window opens with the Insert menu section at the top. See Figure 5-44 and Figure 5-45.
4. Click the drop down arrow and select the desired command.
5. In the multiplier box, enter the number of patients that you want to add to the list or the number of wells that you want to skip and click **Apply**.
6. The Luminex Batch Setup dialog box reflects the new information. Figure 5-45 shows that eight patients were added. The Dilution Factor defaults to 1. Skipped wells and patient wells added to the batch are shown as green wells on the microtiter plate image. The yellow wells indicate sample commands, performed from a well that were locked into the batch from template commands.

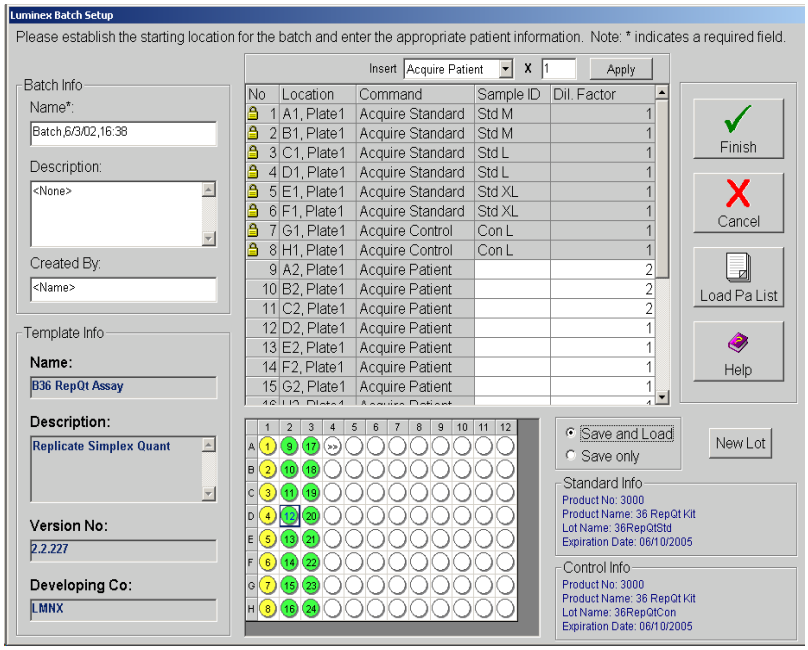


Figure 5-45 Luminex Batch Setup Dialog Box

Open a Batch

Note: You can open "Saved Only" batches using Open Batch

Use this procedure to open a batch that you created earlier (save only). To verify that you opened the correct batch, the batch name and batch description appear on the Run Batch tab when you load the batch.

◆ To open a saved batch to the system for acquisition:

1. Click **Open Batch**. The **Open Batch** dialog box opens listing available batches for selection.
2. Select the desired batch to load, then click **Select**. The system loads the batch as you created it to the Run Batch tab.
3. Click **Eject/Retract**, then click **Start Plate** to initiate batch acquisition.

Delete a Batch

You can delete unprocessed batches (Save Only).

Note: Make sure that the batch that you want to delete is the batch that you selected. Once you delete a batch, you cannot recover it.

◆ To delete an unprocessed batch:

1. On the **File** menu, click **Delete Batch**. A dialog box opens listing only the unprocessed batches in the database.
2. Select the unprocessed batch that you want to delete.
3. Click **Select**. The system deletes the batch that you selected.

Create a Multi-Batch

A multi-batch is a set of batches that you want to process consecutively. You can add batches to the multi-batch from existing batches in your database, or you can create new batches to add to the multi-batch. You can include as many batches as you need in your multi-batch. The software does not limit you to a certain number of batches per multi-batch.

◆ To create a new multi-batch:

1. Click **Create New Multi-Batch**.
2. In the **Luminex Multi-Batch** dialog box, click **Add Batch** to add an existing batch to the multi-batch. See Figure 5-46.

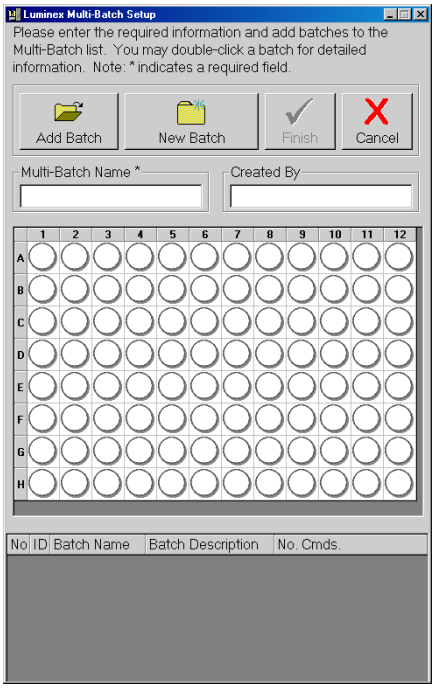


Figure 5-46 Luminex Multi-Batch Setup Dialog Box

3. Select the batch that you want to process first in the multi-batch and click **Select**. The batch appears beginning in well A1 of the microtiter plate on the **Luminex Multi-Batch Setup** dialog box. A thick red line appears above well A1 and another thick red line below the last well in the batch. These lines separate this batch from subsequent batches that you add to the multi-batch. All wells in the batch are labeled with a 1 to denote it as the first batch in the multi-batch. Subsequent batches that are added to the multi-batch will contain 2, 3, and so on to show these locations in the multi-batch.

4. Repeat steps 2 and 3 as often as you need to add all the batches you want in the multi-batch.

5. To create a new batch to add to the multi-batch, click **New Batch**.

6. In the **Open Template** dialog box, select the template that you want to use in your new batch, and then click **Select**.

7. In the **Luminex Batch Setup** dialog box, enter the batch name, creator name, and batch description. See Figure 5-47.

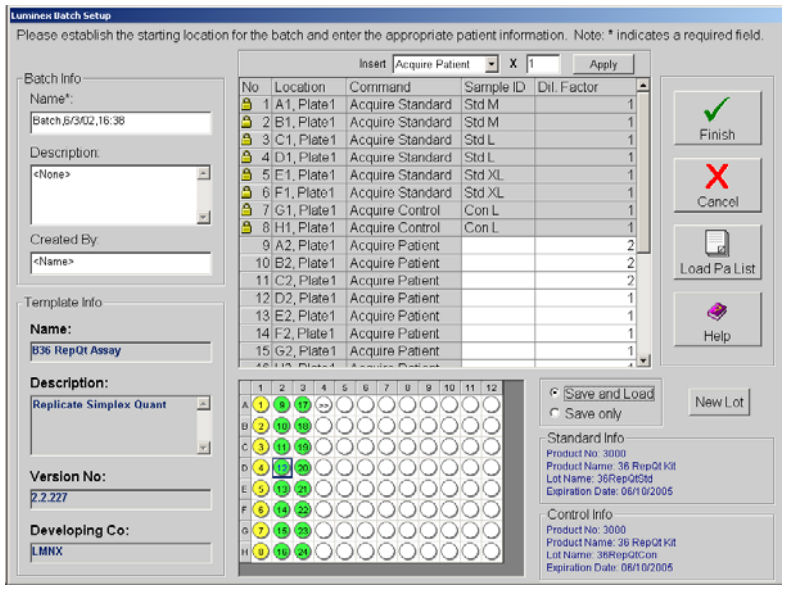


Figure 5-47 Luminex Batch Setup

Note: Batches may span more than one plate. When the first plate is full, a blue line appears to separate the columns of the first plate and those of the second plate.

Note: If any of the acquire sample commands within the template of the batch has an unassigned Sample ID, the system applies the first patient ID in the list to the unassigned sample acquisition command. The system appends any remaining patient IDs to the end of the command list in order as they appear in the patient list.

Note: Multi-batches may span more than one plate. A blue line separates the first plate and the second plate. A scroll-bar appears along the bottom of the microtiter plate image so you can view additional plates.

8. Enter the Patient/Sample IDs and dilution factors in the appropriate rows. You can manually enter the Sample ID or scan in using the system barcode scanner. If the Sample ID row is blue, the software will not apply the sample IDs until it is white.

9. If you want to add a patient list to this batch, click **Load Patient List**. Select a patient list text file to append to the batch and click **Open**. The patients from that text file append to the latest batch added to the multi-batch. The patient list appends to the first well occupied without a command.

   If you have defined patients in batch setup and have added a patient list, the patient list is placed in the first available empty well location following the defined patient commands.

10. Click **Save and Load**, then click **Finish**. The batch is added to the multi-batch.

    To reassign the positions of the batches within the multi-batch, see “Change Start Acquiring Data Location in Multi-Batches” on page 5-64 for more information.

    Different batches within the multi-batch are separated by thick red lines above the first well and below the last well of each batch.

11. After all batches are added, enter the multi-batch name and creator name, then click **Finish**. The Run Batch tab opens

representing the batches you selected or created on the microtiter plate.

12. Click **Eject** and load the first plate of the multi-batch.
13. Click **Start Plate** to begin acquiring data from the multiple batches in the sequence that you set up.

Re-run or Recover Incomplete Batch

An incomplete batch can be caused by situations such as a power failure, software failure, marking a batch for deletion, or clicking Cancel All. Use this procedure to re-run or recover an incomplete batch.

◆ To open an incomplete batch:

1. On the **File** menu, click **Open Incomplete Batch**. The **Open Run** dialog box opens. Select the batch you wish to recover from the list.
2. Click **Start** to continue where the batch left off.

Note that a comment is added to the batch to indicate that the batch is being rerun.

Open a Multi-Batch

Use this procedure to open a multi-batch that you created earlier for acquisition.

◆ To load a multi-batch for acquisition:

Note: Each batch within a multi-batch appears on the list of available multi-batches. The software differentiates them according to the batch ID, name, and description. However, the software gives all batches comprising a multi-batch the same multi-batch ID number and name.

1. Click **Open Multi-Batch**. The **Open Multi-Batch** dialog box opens listing the available multi-batches for selection.
2. Select any one of the batches having the desired multi-batch name.
3. Click **Select**. The system loads the multi-batch to the Run Batch tab.
4. Click **Eject/Retract** to eject the plate holder.
5. Load the first microtiter plate onto the plate holder.
6. Once you load the plate to the system, click **Start Plate** to retract the plate holder and begin acquiring the multi-batch data.

Process Multiple Plates

You can process multiple plates per batch or multi-batch. After loading a batch or multi-batch that spans more than one plate, a new

plate appears to the immediate right of the existing plate image on the screen. A dark blue line separates the adjacent columns of the two plates. See Figure 5-48.

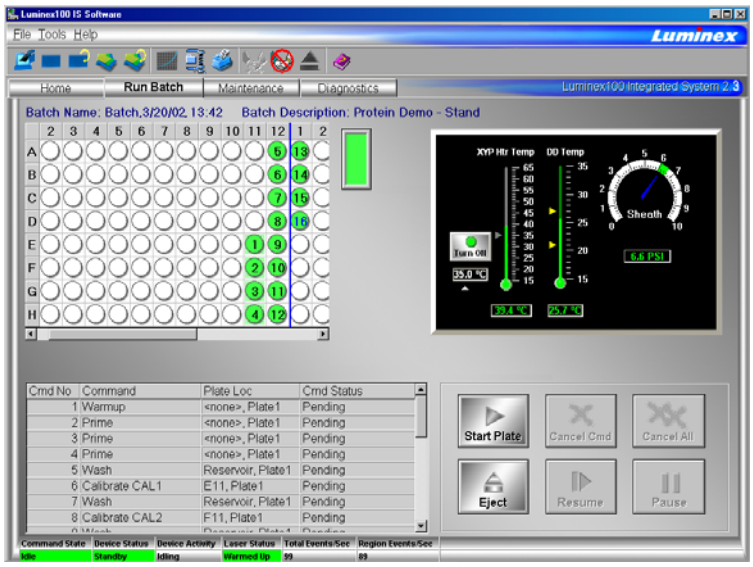


Figure 5-48 Processing Multiple Plates

Note: You may need to scroll to the right of the screen to see additional plates.

During acquisition for multiple plate batches, after the first microtiter plate has been acquired, the system pauses and prompts you to insert the next plate.

◆ To process multiple plates during a batch or multi-batch:

1. Create the batch or multi-batch. See “Create a New Batch” on page 5-50 or “Create a Multi-Batch” on page 5-55 for more information.
2. Load the batch or multi-batch. See “Open a Batch” on page 5-54 or “Open a Multi-Batch” on page 5-58 for more information.
3. On the **Run Batch** tab, click **Start Plate** to begin processing the batch. When the initial plate is through, the system pauses and displays the "Insert Next Plate" message in red. See Figure 5-49.

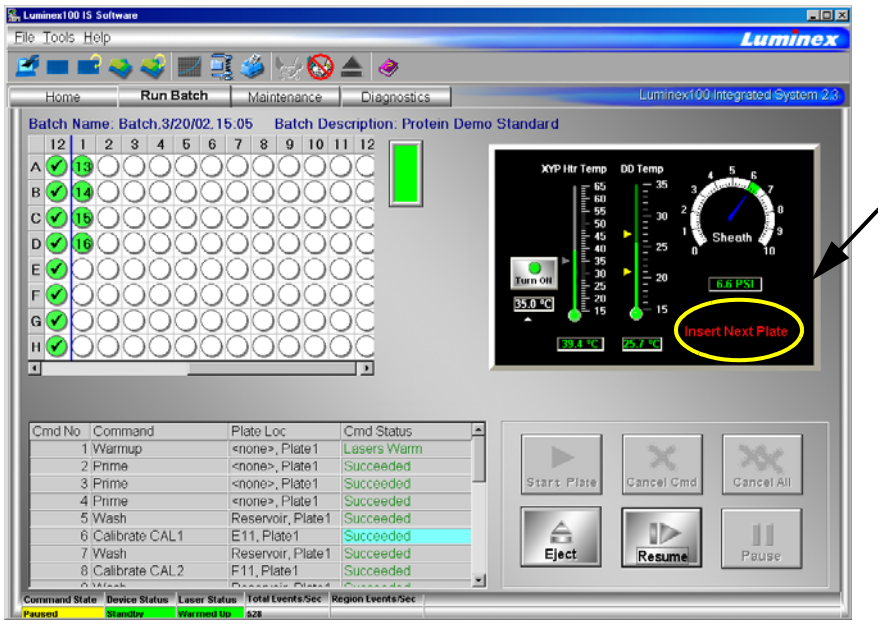


Figure 5-49 Insert Next Plate Prompt

4. Click **Eject,** then remove the acquired plate and load the next plate for processing.

5. Click **Resume**. The system resumes the acquisition process.

Scan In New Samples with a Barcode Reader

The barcode reader lets you quickly enter the sample identification numbers or accession numbers. The barcode reader is particularly useful when you have many samples to enter into the system.

Use the Code 128 barcode label type when scanning barcode labels into the system as patient identities.

◆ To scan samples into the system using the barcode reader:

Warning: Laser light. Do not stare into the beam. Class II laser product.

1. Aim the barcode reader's beam to read the middle of the barcode series, horizontally. See Figure 5-50.

Note: The barcode reader beam must encompass the entire set of bars in the barcode. Shaded area of Figure 5-50.

Figure 5-50 Barcode Reader Beam Aimed Across Code

2. Squeeze the barcode reader's trigger. The beam activates and reads the barcode. The barcode information appears in the appropriate row.

3. Visually verify that the barcode data scanned correctly. It is critical that you scan (or enter) the correct identification number.

Add a Patient List

You can apply a Patient List to any batch or multi-batch **only** during batch setup in the **Luminex Batch Setup** dialog box.

Note: You can create a Patient List text file using Windows Notepad or a text editor.

The Patient List text file must meet the following requirements:

- The first line of text in the file must be "LX100IS Patient List".
- The second line of text in the file must be "[Accession#, Dilution Factor]".
- Any following lines of text should be only in the format, "x, y".
  Where x = accession ID number for the patient (patient identifier string) and y = dilution factor.
- The dilution factor is **optional**, but if entered, must be a numeric value.
- If the dilution factor is omitted, the system defaults to one.
- Patient list entries are case sensitive. This applies to entries made through the graphical user interface or in a file.

Review the file before saving for the batch. The format must be like the following example or it will not load properly. Once you load the patient list to the new batch, then you may make edits to the dilution box. Before you save the newly created batch, you need to double check all Sample IDs before clicking **Save Only** or **Save and Load** prior to clicking **Finish**.

An example of a typical patient list file:

```
LX100IS Patient List
[Accession#, Dilution Factor]
a001,1
a002,2
a003,1
b001,4
b002,0.6
c917,4
cee4gf,1
```

◆ To add a Patient List text file while creating a batch or multi-batch:

1. On the toolbar, click **Create New Batch** or **Create New Multi-Batch**. The **Open Template** dialog box opens.

2. Select a template to create a new batch and click **Select**. The **Luminex Batch Setup** dialog box opens showing the template commands and the microtiter plate representation. For multi-batches the **Luminex Multi-Batch Setup** dialog box opens. See Figure 5-51.

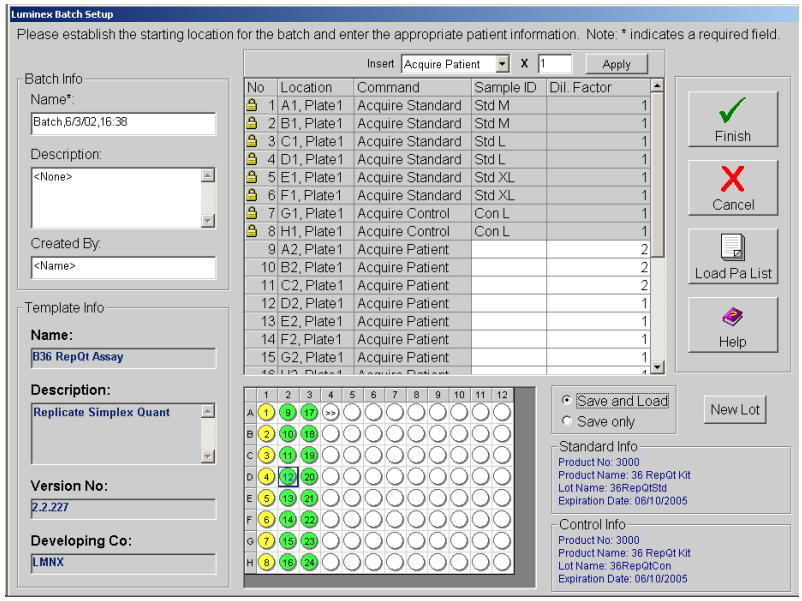


Figure 5-51 Luminex Batch Setup Dialog Box

3. Click **Load Patient List**. The **Open Patient List File** dialog box opens. See Figure 5-52.

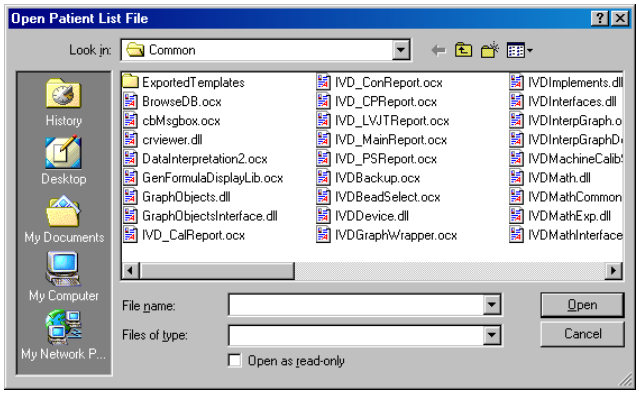


Figure 5-52 Open Patient List File Dialog Box

Note: If any of the acquire sample commands within the template of the batch has an unassigned value, the system applies the first patient ID in the list to the unassigned sample acquisition command. The system appends any remaining patient IDs to the end of the command list in order as they appear in the patient list.

4. Double-click on a patient list text file to append to the batch. The patients from that list append to the first unassigned available well. If all patient IDs in the batch or multi-batch are identified, the system appends the patient list to the first empty location after the batch's or multi-batch's last command list activity.

   Choose whether to save the batch or multi-batch for later use. Click **Save only** to save the batch or multi-batch. To run it after you finish creating it click **Save and Load**.

5. Click **Finish**. The system saves the batch or multi-batch for later use or it loads it for immediate use according to the decision you made when creating it.

Edit a Patient List

Use this procedure to open a previously processed batch and correct the batch's sample names and dilution factors. You can delete a sample from a batch. If you change the patient information in a batch including those imported from a patient list, the system automatically notes the change in the comments box of the sample table within the database.

While editing the database, the system marks the changes you make in red text. This distinguishes the change from the patient information entered into the original batch. Figure 5-53 shows an edited patient list.

Note: Patient list entries are case sensitive. For example, John Doe, John doe, and john Doe are three unique entries. This applies to entries made through the graphical user interface or in a file.

◆ To edit a patient list:

1. On the **File** menu, select **Edit Patient List**. The **Open Batch** dialog box opens.

2. Select the desired batch containing the patient list that you want to edit and click **Select**. The **Edit Patient List** dialog box opens similar to Figure 5-53.

3. Edit the desired patient and associated dilution factor information. Click **Finish** to accept your edits and close the dialog box.

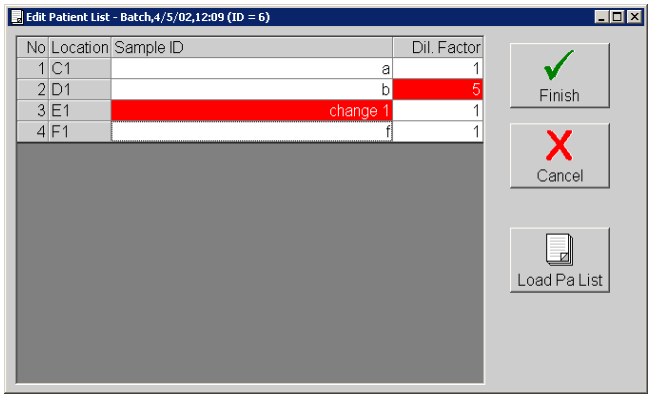


Figure 5-53 Edit Patient List Dialog Box

Change Start Acquiring Data Location

While creating a batch, you can define where to begin acquiring samples; that is, in a location other than the first available empty well. Once you open a batch for processing, you cannot change the location where data acquisition begins.

- To establish where to begin acquiring data on the microtiter plate during batch creation:

1. From the microtiter plate representation in the **Luminex Batch Setup** dialog box, click the first well for sample acquisition.
2. Drag the highlighted well to the desired start location on the microtiter plate. The display updates to show the wells new location. Empty wells in front of the new starting well now appear red.

   When you process this batch, the system starts acquiring data in the well indicated.

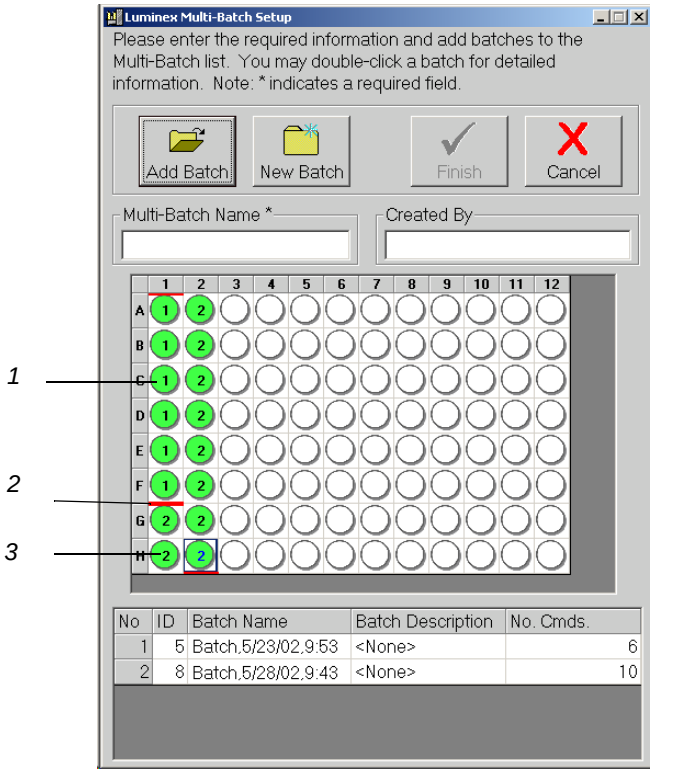
Change Start Acquiring Data Location in Multi-Batches

You can change the location for multi-batches to begin acquiring data.

- To change the locations for beginning acquisition for batches in a multi-batch:

1. On the toolbar, click **Create New Batch** or **Create New Multi-Batch**. The **Luminex Multi-Batch Setup** dialog box opens. Refer to “Create a New Batch” on page 5-50 or “Create a Multi-Batch” on page 5-55 for more information.

2. From the microtiter plate representation in the **Luminex Batch Setup** or **Luminex Multi-Batch Setup** dialog box, click the first well for sample acquisition. See Figure 5-54.



1. First batch 2. Separator Line 3. Second batch

Figure 5-54 Selecting Multi-Batch Starting Data

3. Drag the highlighted well to the location on the microtiter plate where you want to begin acquiring data. For a multi-batch, ensure each additional batch is in its desired location. The display updates to show the wells for acquisition in its new location. The empty wells in front of the new starting well now appear red in the Batch Setup box or white in the Multi-batch Setup box.

   When you process this batch, the system begins acquiring data from the well indicated.

   You do not need to run batches in consecutive wells within a multi-batch. There can be empty wells between batches.

Assign Sample Dilution Factors

You must indicate the sample dilution factor so the sample analysis in quantitative tests is accurate. The system multiplies the result by

the dilution factor for reporting. You must assign dilution factors as you create a batch.

Do not use dilution factors for qualitative testing.

You define the dilution factors on a sample-by-sample, or patient-by-patient basis. The list displays each sample's accession number and dilution factor in relation to its well position.

◆ To assign sample dilution factors:

1. On the **File** menu, click **New Batch**. The **Open Template** dialog box opens.
2. Select the desired template and click **Select**. The **Luminex Batch Setup** dialog box opens. See Figure 5-55.
3. Highlight or select the item that uses the dilution factor that you are setting. You cannot change any item that is grayed out or locked into the command list.

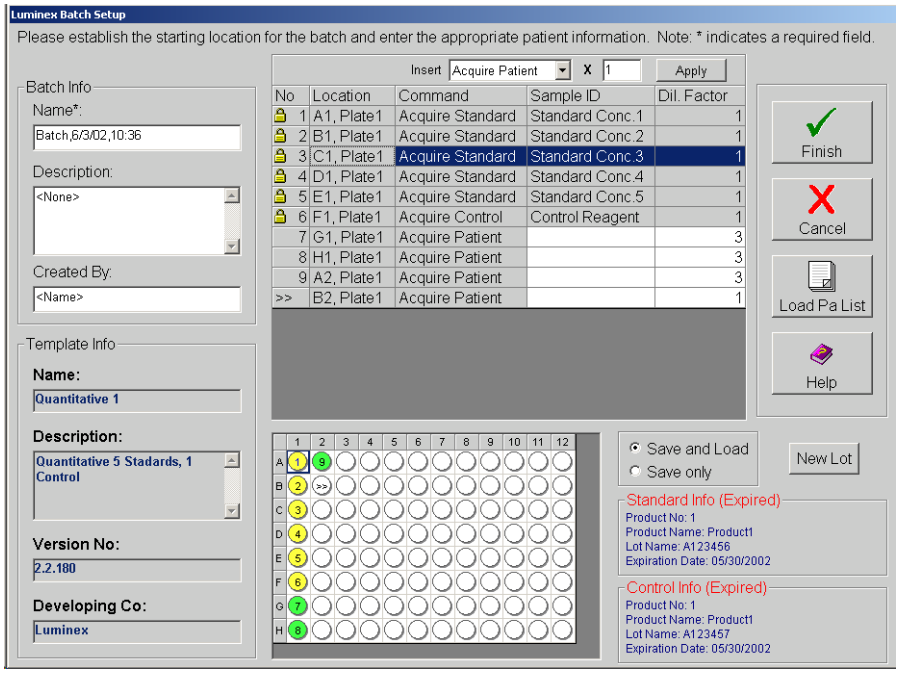


Figure 5-55 Luminex Batch Setup for Dilution

4. To change the dilution factor, click the **Dil. Factor** box. The white background indicates that you can enter text. Enter each dilution factor as a decimal, not as a ratio.
5. Click **Finish**. The system saves the information you entered.

Copy Batch Information to Clipboard

You can copy the following information to the clipboard:

- At the Run Batch tab, the four columns in the batch command list
- At the Run Batch tab, the microtiter plate image
- At the Diagnostic tab you can copy the Message Log

◆ To copy information from the current batch:

Note: The system **does not** allow you to copy or paste information while interpreting or analyzing data.

1. Click over the desired area to copy.
2. Press the **Ctrl+C** keys on the keyboard or right-click and select **Copy** from the menu.
3. At the **Command Information** dialog box, click **OK**. The information is copied to the clipboard. If you copy the microtiter plate image or Command List areas on the **Run Batch** tab, the **Command Information** dialog box does not appear.

Paste Batch Information to a Document

◆ To paste information from the current batch into a document:

1. Open the document where you want to paste the information. Click the cursor at the insertion point in the document.
2. Press the **Ctrl+V** keys on the keyboard or right-click in the document and select **Paste** from the drop-down command list. The copied information appears at the insertion point in the document.

Clear a Batch From the System

The Clear Batch command clears the entire batch from the Run Batch tab or the Message Log on the Diagnostic tab.

◆ To clear a batch from the system:

Note: Once you choose to clear the batch and verify that you want to continue with the command, you can regain the cleared batch if it has not been run by clicking **Open Batch**.

1. Right-click on the area to clear.
2. Click **Clear** in the dialog box.
3. Click **Yes** to confirm that you want to clear the batch.

Create a New Advanced Batch

Use New Advanced Batch to acquire data without creating a template. It writes raw data results to a simple csv file format. You can define parameters for samples, gates, regions, events, on-plate and off-late commands. This feature does not store the results in the Luminex 100 IS data base or allow you to perform data analysis on acquired batches.

◆ To create a New Advanced Batch:

1. Select **Acq. Detail tab**.
2. On the Acquisition Detail toolbar, click **New Advanced Batch**. The **Options** Dialog Box opens with the **General** tab displayed. See Figure 5-56.

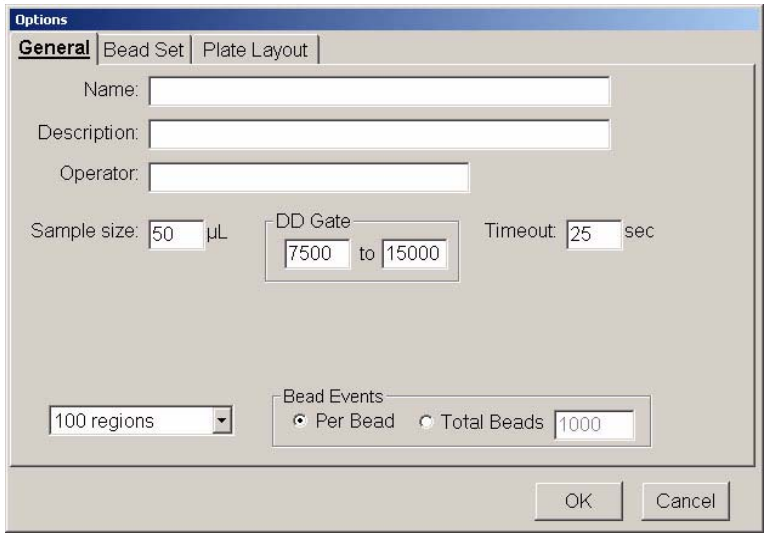


Figure 5-56 Options Dialog Box—General Tab

3. Enter the **Name**, **Description**, and **Operator** information.
4. Edit the following information as desired:
   - **Sample Size** - use values from 20 to 200 µL. To avoid air uptake, we recommend that your sample well contains at least 25 µL in addition to the sample size.
   - **DD Gate -** use values within the range of 0 to 32767.
   - **Timeout -** use values of 0 to 400, where 0 = no timeout.
5. Click the arrow down next to **100 regions** to select the desired bead map. The available bead maps are 25, 50, 64, and 100 (default) regions. Select whether you want the Bead Events results to be displayed as **Per Bead** or **Total Beads**. If you select Total Beads, enter the number of total beads in the text box.
   - Select **Per Bead** to continue analyzing until each bead set has met the minimum events as determined on the Bead Set tab.
   - Select **Total Beads** to continue analyzing until the selected beads meet total beads value. Use Total Beads when you are not using all of your selected bead sets in each well. Set the total to desired high value.

Note: Use plates with wells that will hold at least 185 µL (the extra 25 µL from the sample, plus an extra 160 µL that is dispensed back into the well following acquisition).

Note: The Luminex 100 IS software uses only the 100 region bead map. However, at the Acquisition Detail tab, you can view the data for 25, 50, and 100 regions and save the data to a csv file.

6. Click the **Bead Set** tab. Select the checkboxes next to each desired bead set for this batch. Click **Select All** to select all the listed bead sets, or **Deselect All** to deselect all selected bead sets.

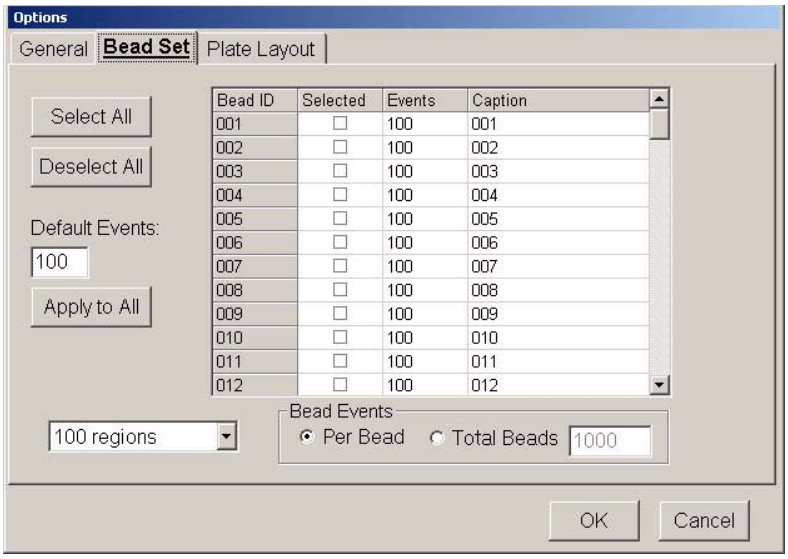


Figure 5-57 Options Dialog Box—Bead Set Tab

7. Edit the **Events** and **Caption** information for each bead set. Edit the **Default Events** box to change the default value. Click **Apply to All** to apply the default value to all bead sets. Table 5-6 lists selection shortcuts.

Table 5-6. Bead Set Tab - Selection Shortcuts

Selected Column	Select desired rows under column and right-click. You can select or deselect.
Events Column	Select desired rows under column and right-click. The values displayed in the “Default Events” box update the selected rows when you click “Apply Default” while right-clicking.
Caption Column	If names are defined under this column, you can right-click selected rows and “Reset” back to normal defaults.
Entire Column	Select an entire column by clicking the column heading (Selected, Events, or Caption).

8. Click the **Plate Layout** tab. See Figure 5-58. On this tab you define commands for the desired wells on the plate. You can define commands that apply to one or more wells, one or more rows of wells, or one or more columns of wells. You can define on-plate or off-plate commands.

Note: The legend at the left side of the tab (No, Cmd Name, and Symbol columns) shows available commands and their colored-coded symbols. Symbol appears in the well when selected from the Command Menu.

Table 5-7. Symbol Color Codes

Symbol	Color
A	Blue
C1	Red
C2	Green
N1	Teal
N2	Purple
W	Olive
D	Black
S	Fuchsia

Note: Wells are always read in rows (letters A to H) and columns (numbers 1 to 12) starting with A1. If partial columns are selected they are still read in the same order. Unselected wells are skipped.

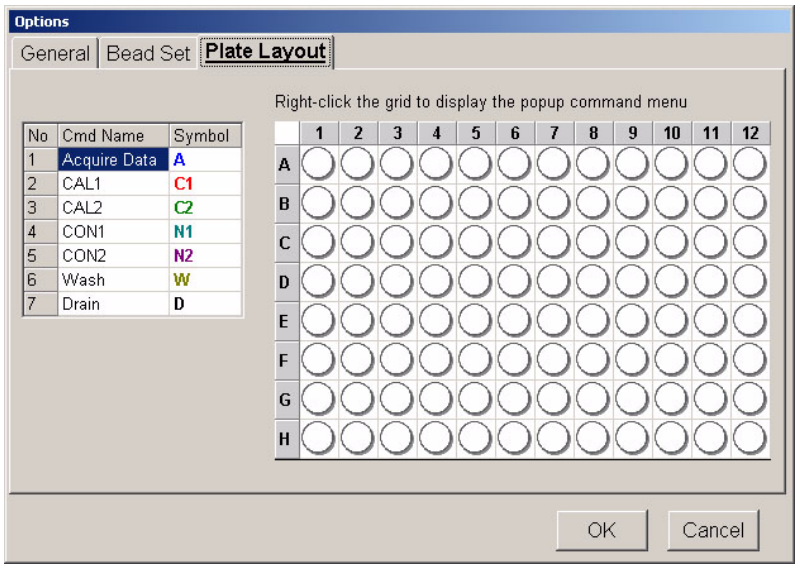


Figure 5-58 Plate Layout Tab

9. Select wells. To select a single well, click the well. To select multiple wells in a group, click and hold the mouse button with the cursor over the first well, then drag the cursor around the desired wells. To select a row or column click the letter or number of the row or column.

10. Select plate commands. Right-click over the selected wells to display the Command menu. See Figure 5-59. Select the desired command. The associated command symbol appears in the designated plate well. To make a correction, select the wells (selected wells are blue), right-click over the selected wells to display the Command menu, and then click **Clear Selection** from the list. Table 5-8 (following) lists Plate Layout selection shortcuts.

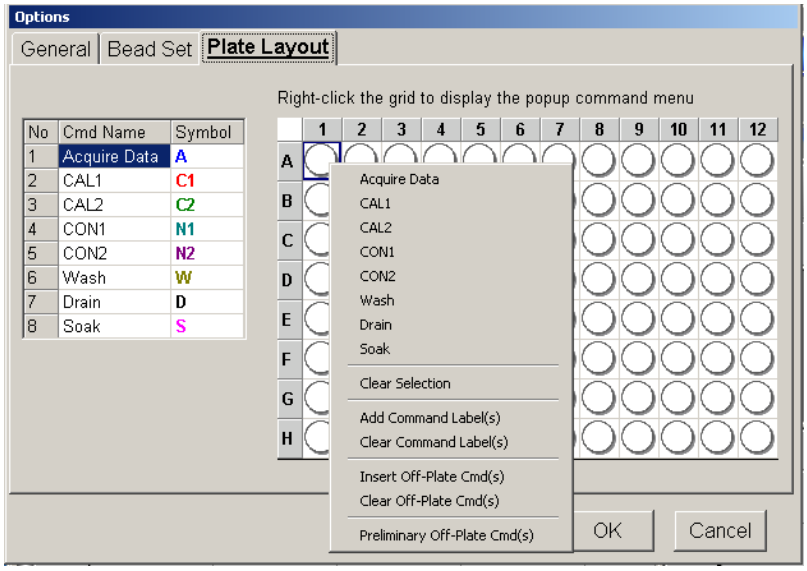


Figure 5-59 Plate Layout Tab Command Menu

11. Establish preliminary off-plate commands. The system performs preliminary off-plate commands before the first well command. To establish a preliminary off-plate command, right-click anywhere over the plate layout and select **Preliminary Off-Plate Cmd(s)** from the menu, double-click the corner marker, or right-click on the corner marker space.The command list dialog box appears similar to Figure 5-60.

    Notice the prompt sentence over the commands: “Establish the off-plate commands to run before the plate begins.” Double-click the desired commands. The commands appear in the list (gray area) to the right. Click **OK** after you select the desired commands. The white corner marker in the top left corner of the plate (above the letter A) turns green to indicate an off-plate command is established. The selected commands run before the plate begins.

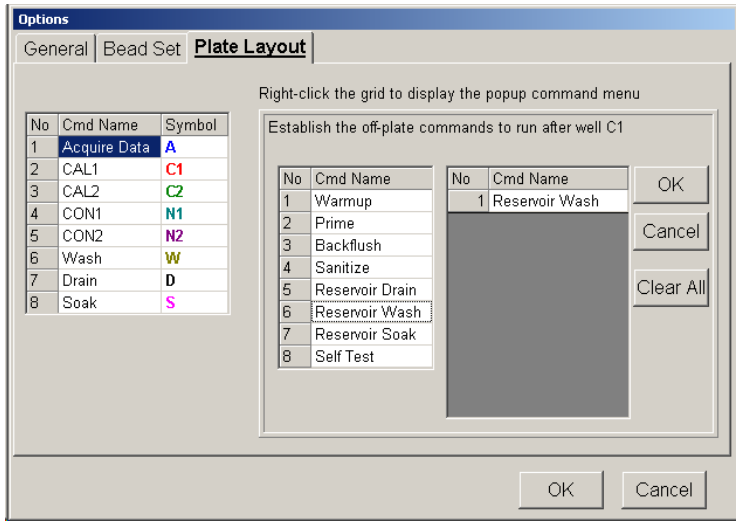
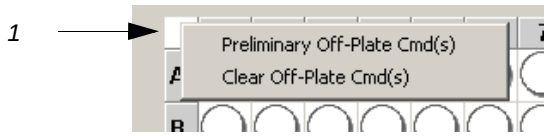


Figure 5-60 Plate Layout Tab, Off-Plate Commands

Note: White corner marker turns green to indicate Preliminary Off-Plate command in effect.

Right-click on corner marker to display menu. See arrow in Figure 5-61.

Clear preliminary off-plate commands. To clear preliminary off-plate commands, right-click on the corner marker or plate layout and select **Clear Off-Plate Cmd(s)**. See Figure 5-61.



1. Corner marker

Figure 5-61 Preliminary Off-Plate Command Marker

12. Establish insert off-plate commands. You can establish insert off-plate commands that run after a single well, after a range of wells, or after rows or columns of wells. The prompt sentence displayed should be appropriate for your selection. For example, if you select row B, the prompt “Establish the off-plate commands to run after wells B1 through B12” appears.

    To establish insert off-plate commands, select the desired wells, then right-click over the plate layout. Select **Insert Off-Plate Cmd(s)** from the menu. Select the desired commands and click **OK**. The background of the established wells turn green.

    Clear insert off-plate commands. To clear insert off-plate commands, select the wells to clear, right-click over the plate layout and select **Clear Selection** from the menu.

13. After you define the information on the **General**, **Bead Set**, and **Plate Layout** tabs, click **OK**. Click **Cancel** to abort.

Table 5-8. Plate Layout Tab - Selection Shortcuts

Click column heading to select entire column.
Click row heading to select entire row.
Click the top left corner of the plate to select entire plate.
Each well can have a series of off-plate commands that run before the next well is read.
You can insert preliminary off-plate commands that run before the first well.

Background Samples

Background samples are commonly used in the assay process in the Luminex 100 IS 2.3 system. Although recommended, the discretion on whether to use or not is left to the assay or kit developer. If the background samples are to be included they have been defined in the assay template.

Background samples are samples with no active test substance. The system uses background samples to remove assay background noise from the sample results.

Typical background samples contain coupled beads, assay buffer, detection reagents, and reporter fluorophore. Background samples do not contain target analytes.

If the background sample is designated accordingly, the system subtracts the background sample's reported fluorescence from all other samples in a batch to report net median fluorescence intensity (MFI).

If a batch contains more than one background sample, the fluorescence values of the two background samples are averaged together and subtracted from the other samples to obtain a net fluorescence intensity (MFI).

Templates

When creating batches or multi-batches, you must select a template to associate to the batch.

Templates are predefined command sequences set by assay kit manufacturers to use during batch acquisition. Refer to the *Luminex 100 IS Developer Workbench Guide Version 2.3* for template details.

Caution: Do not alter predefined templates.

Import a Template

Your assay kit may provide a kit-specific template, supplied on a diskette or CD. You need to import new templates to the system only once. Templates include standards, controls, both standards and controls, maintenance commands, and acquisition commands.

◆ To import a template from a diskette or CD:

1. Insert the kit's diskette or CD into the appropriate drive.
2. On the **File** menu, click **Import Template**. The **Import Template** dialog box opens. See Figure 5-62.

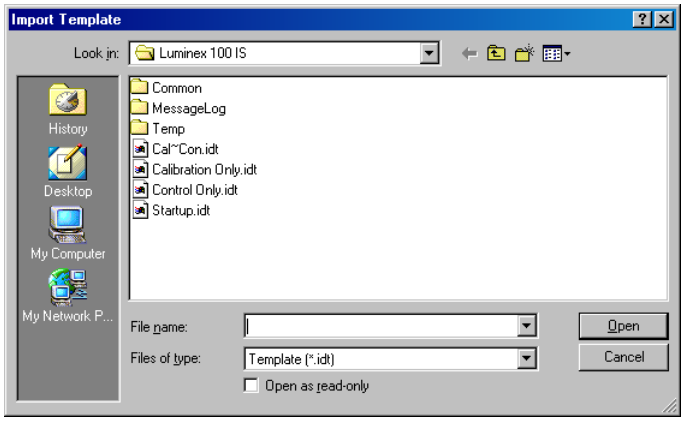


Figure 5-62 Import Template Dialog Box

3. Click the **Look in** drop-down arrow and navigate to the diskette or CD drive containing the template. The diskette drive is typically drive A and the CD drive is typically drive D.
4. The kit manufacturer's template appears on the selection list. Click the name of the template.
5. Click **Open** to load the template.

Assay Lot Management

You can edit standard and control lot information. Once a lot is used, changing or modifying it will prompt you for a new lot name. This includes batches that have been setup, but not yet acquired.

You can modify known lot concentration values. If you change the known concentration for a used lot, the system prompts you to enter a new lot name. If you change the lot concentration values for an unused lot, the system updates the lot with the new lot concentration values.

Once you import a template, you must enter lot information for the standard and control reagents as specified in the template. This lot information is used for every batch setup using this template until changed.

For assay reagents specified in templates, the system allows you to create new lots, edit lot information, select pre-existing lots for reuse, or import and export lots.

When editing lot numbers follow these lot handling rules:

- If you have entered lot information for a template, but you have not used the template to setup a batch, then you can edit the lot value.
- If you have entered lot information and you have used the template to setup a batch (even if it has not yet been acquired), then you can edit the lot values. However, you must rename the lot.

Lot procedures include:

- Create New Lots
- Edit Lot Information on an Unused Template
- Edit Lot Information on a Used Template
- Import a Lot to Existing Template
- Export Lot from Existing Template

Create a New Lot

◆ To create a new lot:

1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens. See Figure 5-63.

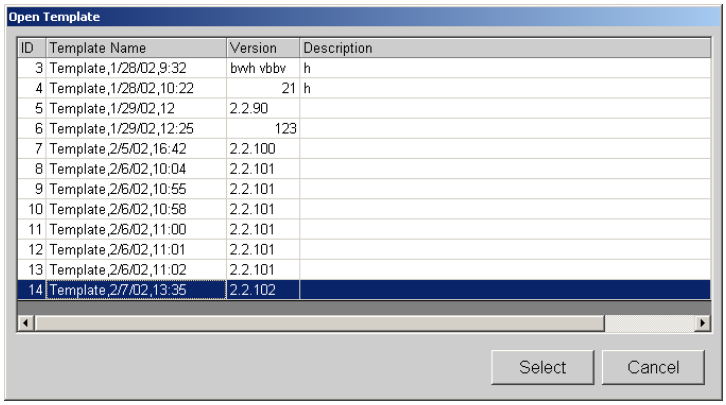


Figure 5-63 Open Template Dialog Box

2. Highlight the template that will use the new lot information and click **Select.** Then, continue with substep “a” or” b”.

   a.) If this is a new template with no associated lot information, a **New Standard Lot** or **New Control Lot** dialog box opens as appropriate. You must enter the standard and control names to continue. See Figure 5-64. Once you enter the names, the **Update Lot Information** dialog box opens. See Figure 5-65.

   b.) If this is a template with associated lot information, the **Update Lot Information** dialog box opens. To create a new lot when there is an existing lot, select the **New Lot** button from the Standard or Control section of the dialog box. See Figure 5-65. A **New Standard Lot** or **New Control Lot** dialog box opens. Enter the standard or control lot name. See Figure 5-64.

3. Click **OK**.

Note: Depending on the types of products associated with the template that you select, the screen may vary from the example in Figure 5-65. That is, if you are creating only standard lots, then only the upper part of the screen displays.

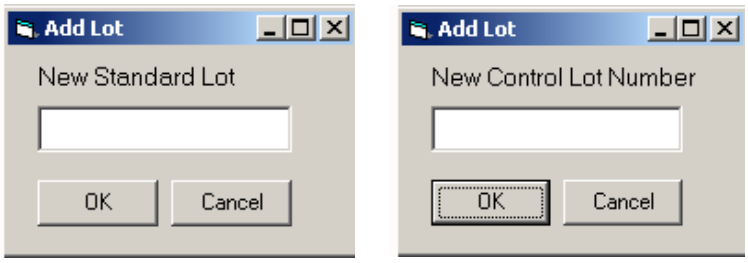


Figure 5-64 Add Lot Standard and Control Dialog Boxes

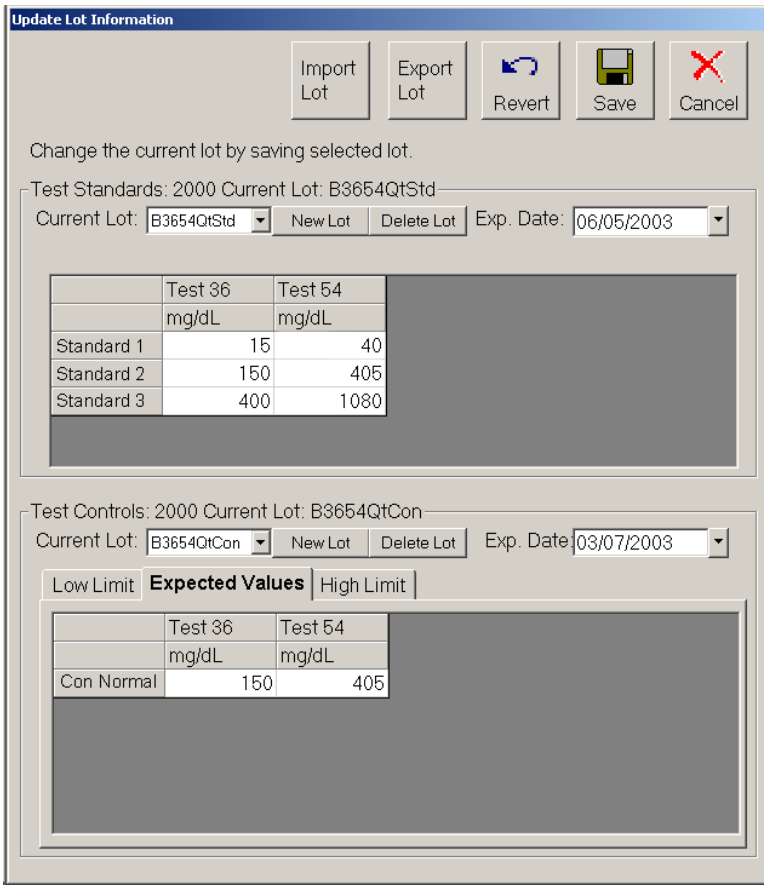


Figure 5-65 Update Lot Information Dialog Box

4. Click the **Exp. Date** arrow and select the date from the calendar.
5. Enter the standard concentration values provided in the kit manufacturer's instructions. See Figure 5-65.
6. Enter the control reagent values. The controls are divided into 3 separate tabs: Low Limit, Expected Value, or Mean and High Limit. All information must be defined to enable the **Save** button.
7. Click **Save**. The system applies the lot you just created to the template.

Edit Lot Information on an Unused Template

◆ To edit information for an existing lot:

1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens. See Figure 5-66.

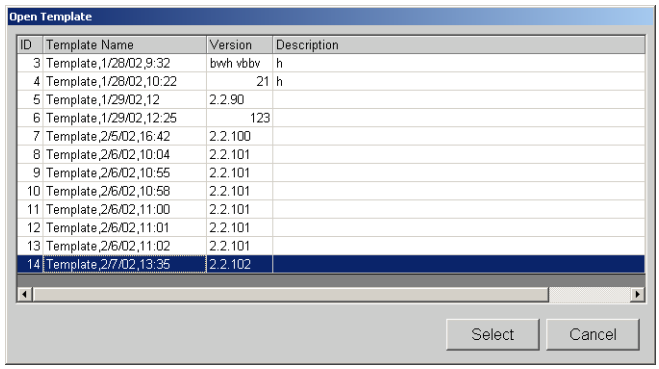


Figure 5-66 Open Template To Update New Lots

2. Highlight the template that you want to edit and click **Select**. The **Update Lot Information** dialog box opens. See Figure 5-67.

3. Change or edit the expiration date and the lot concentration values.

4. Click **Save**. The system updates the lot changes and applies them to the template. **The Update Lot Information** dialog box closes.

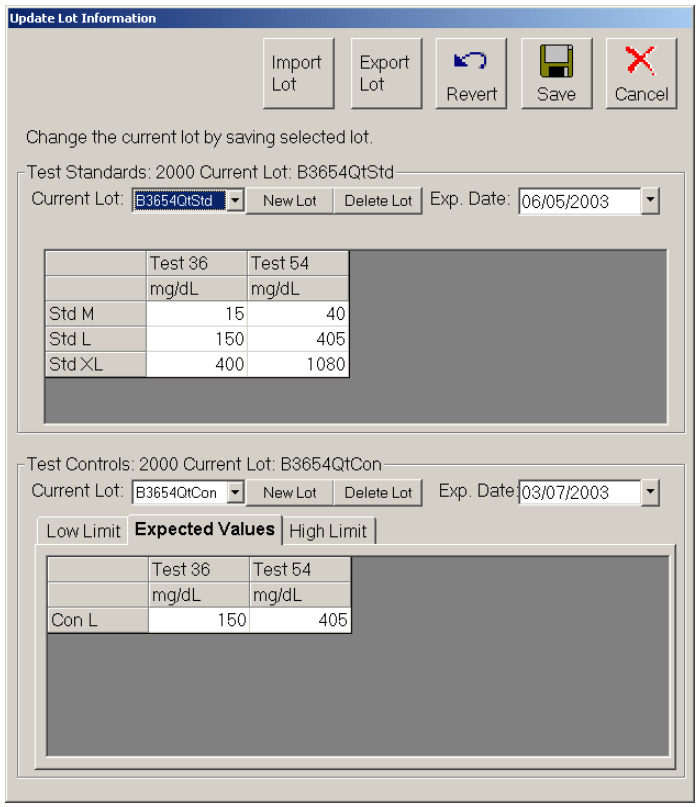


Figure 5-67 Update Lot Information Dialog Box

Edit Lot Information on a Used Template

- To edit lots on a used template (may have new lot number of reagents, but are using same template):

1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens. See Figure 5-68.

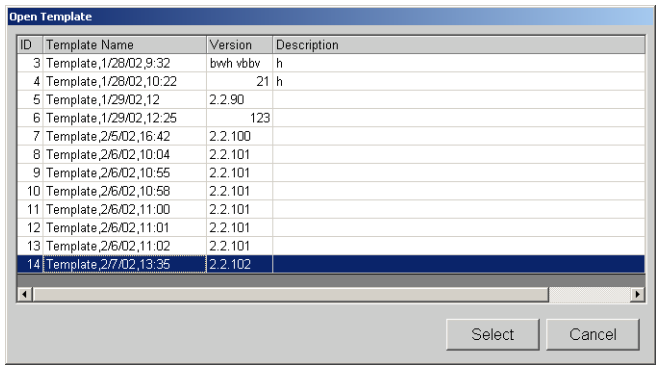


Figure 5-68 Open Template To Update New Lots

2. Double-click the template that you want to edit. An **Update Lot Information** dialog box opens. See Figure 5-67.

3. Change or edit the lot concentration values.

4. Click **Save**. The system alerts you that this lot has been used to setup a batch and that you must create a new lot to continue. See Figure 5-69.

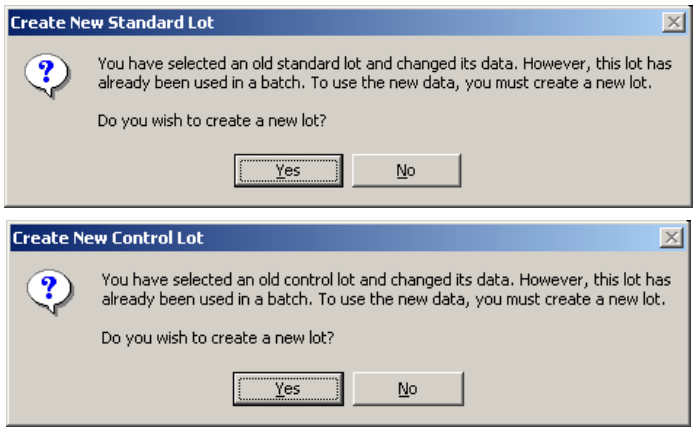


Figure 5-69 Updating Used Template Notification Dialog Boxes

5. Respond to the Create New Standard Lot or Create New Control Lot with **Yes** or **No** and rename when the **New Lot Number** dialog box opens.

Import a Lot to an Existing Template

Use this procedure to import a lot to an existing template from another computer, from a diskette, or from a CD ROM.

◆ To import a lot to an existing template:

1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens. See Figure 5-66.
2. Select the template to receive the imported lot and click **Select**. The **Update Lot Information** dialog box opens. See Figure 5-70.
3. Click **Import Lot**. The **Open** dialog box opens.
4. Navigate to the desired drive's folder and select the lot that you want to import and click **Open**. The lot imports into your template.

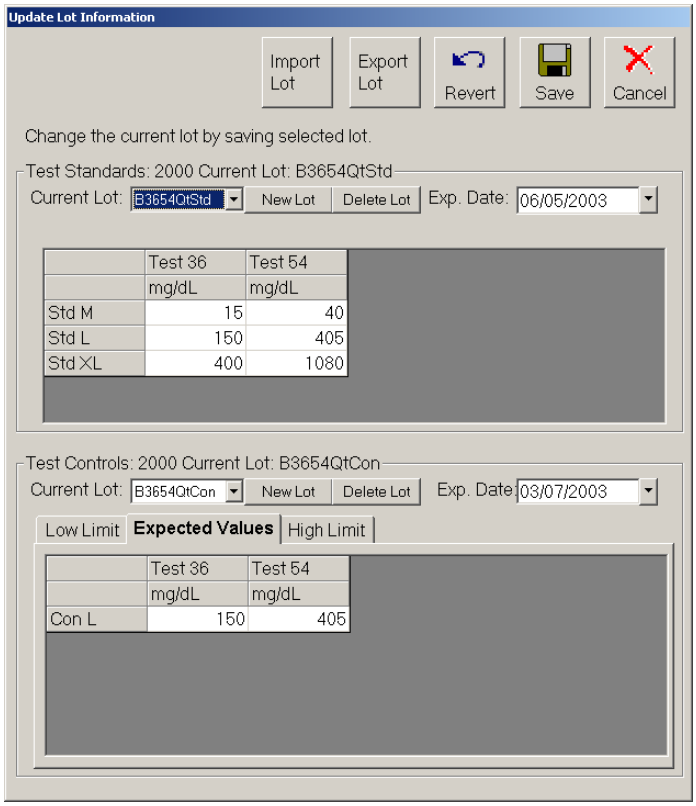


Figure 5-70 Update Lot Information Dialog Box

Export a Lot from an Existing Template

Use this procedure to export a lot for use on another instrument.

◆ To export a lot from an existing template:

1. On the **Home** tab, click **New Lot**. The **Open Template** dialog box opens. See Figure 5-66.
2. Double-click the template containing the lot to export. The **Update Lot Information** dialog box opens. See Figure 5-70.
3. Click **Export Lot**. A standard or control confirmation dialog box opens verifying that you want to export the current lot for the standard or control. See Figure 5-71.

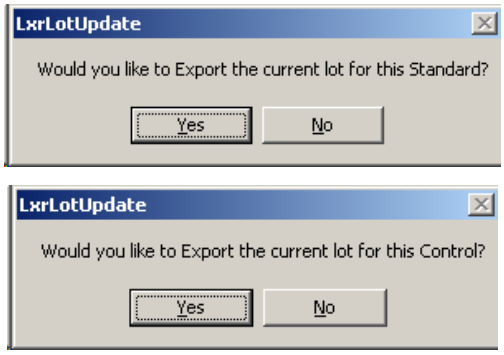


Figure 5-71 Export Confirmation Dialog Box

Note: Depending on the template and its associated products, you may have standards and controls or only standards. Standards and controls can be grouped into the same lot number.

If you want to export the lot information for the standards, click **Yes**. If you only want to export the lot controls, click **No**. A second dialog box opens to verify if you want to export the current lot as a control.

After responding to the confirmation dialog boxes, regarding standards or controls, a **Save As** dialog box opens.

4. Click the drop-down arrow to select the **Save in:** location where you want to save the lot information.
5. Enter the lot file name into the appropriate box.
6. Click **Save**. The system saves the lot.

Replicates

You can run any sample in replicate, including standards, controls, backgrounds, and unknowns. Use this feature to run a single substance an unlimited number of times, minimizing well to well handling errors; thereby recovering a more accurate value for that substance.

Replicate samples are defined by their Sample ID. Samples with identical Sample ID's are analyzed as replicates.

For standards, controls, and background samples the kit manufacturer defines the number of replicates in the Template Setup Wizard.

You define unknown replicates during the Batch Setup process.

Generate a Standard Curve

When kit manufacturers create templates they choose one of two methodologies to generate standard curves:

- Fit of All Standards (default)
- Mean of Replicates

The assay developer defines the curve fit generation method while creating the assay template.

The system default is to generate the curve fit according to the fit of all standards method. When generating a curve fit according to the fit of all standards, the system plots all standards to define the curve.

If the curve is generated from the mean of replicates, the system determines the fluorescent value for each of the replicate standards, then calculates the mean fluorescence of all replicates. The system plots the average (mean) of the replicate standards on the standard curve. Luminex offers this method to reduce the time it takes to calculate the standard curve.

If the system detects that you validate or invalidate a sample, the change affects the final results. The system flags the change and enables the Recalculate button so you can recalculate your results after changing data. Click **Recalc** to recalculate data. Checking the auto box below Recalc causes the system to automatically recalculate the results after each change.

Regardless of how the system generates the curve fit, the system averages replicate test results for all samples (standards, controls, or unknowns) to determine the “reported” test results labeled as “AVG”.

Plate Commands

The system acquires samples based on various plate commands. The plate commands are:

- Start Plate
- Pause
- Resume
- Cancel Command

  - Cancel All
  - Eject/Retract

- You can perform plate commands during sample acquisition.
- You can perform nonplate commands (Prime, Reservoir Wash, Sanitize) between samples.

Start Plate

The Start Plate command begins the acquisition process. During acquisition, the system draws sample from the microtiter plate for processing.

As the system processes data, the system analyzes whether the sample passes predetermined criteria or not. If a sample fails, the system flags that sample and acquisition continues on to the next sample.

◆ To start acquiring sample from a microtiter plate:

1. Check the sample probe vertical height adjustment and adjust if needed. Refer to Appendix B for sample probe adjustment procedure.
2. Create or open the batch that you want to process. Refer to “Create a New Batch” on page 5-50 or “Open a Batch” on page 5-54 for directions.
3. Prepare the microtiter plate with samples for processing.
4. Click **Eject/Retract**. Place the microtiter plate on the plate holder with well A1 in the upper-left corner. Ensure that you carefully follow the kit manufacturer’s directions.
5. On the **Run Batch** tab, click **Start Plate**. The system retracts the plate and begins processing the batch’s template commands. It acquires the samples from the wells as the commands appear on the template.

   The system takes the specified volume for testing. A horizontal progression bar appears on the Run Batch tab to show the status of each sample acquisition. After each sample is analyzed, approximately 160 µL of sheath fluid is dispensed into each well.

As the system analyzes each well, the well shows either a check mark in a green well for successful acquisitions or an **X** mark in a red well for failed acquisitions. Samples may fail for many reasons,

including lack of sufficient events, Cancel command, heater out of range, or plate cancellation.

If Auto-Start Acquisition is selected, the system analyzes samples according to the kit manufacturer's template commands.

Once you start processing a batch, you cannot reacquire data. If you have used a batch for acquisition before, the system will not display it in the open batch list.

Pause

The Pause command temporarily stops the acquisition process. Some examples to pause the system are:

- the temperature goes out of the designated range during acquisition
- to add sheath fluid
- to add a new reagent to your sample group

◆ To pause a command:

On the **Run Batch** tab, click **Pause**. The system completes the current command in process and then pauses the system.

Resume

The Resume command continues an interrupted acquisition process.

◆ To resume a batch:

On the **Run Batch** tab, click **Resume**. The system resumes processing the command list from where it was paused.

Cancel Command

The Cancel Command button cancels the current command in progress.

You cannot cancel the Warmup command.

◆ To cancel a command:

On the **Run Batch** tab, click **Cancel Cmd**.

Cancel All

The Cancel All command cancels the entire batch.

◆ To cancel an acquisition once it has begun:

On the **Run Batch** tab, click **Cancel All**. The current series of commands or batch acquisition is cancelled.

Note: To recover an incomplete batch, click **Open Incomplete Batch** on the **File** menu. In the **Open Run** dialog box, click **Start** to continue where the batch left off.

Upon cancelling, the system stops its activity regardless of its status. The system highlights the well in yellow indicating the ending acquisition process.

Eject/Retract

The Eject/Retract command ejects or retracts the microtiter plate from its current position.

- To eject or retract the microtiter plate:

  On the **Run Batch** tab, click **Eject/Retract**.

Analyze Batches and Multi-Batches

You can analyze an acquired batch using the analysis features of Qualitative and Quantitative algorithms. The algorithm is determined by the kit manufacturer during template creation.

Qualitative analysis—determines the results as either positive or negative, reactive or non-reactive, and so on. The system is also flexible in defining custom result ranges, such as negative, low positive, high positive, and so on. Refer to the Creating Templates section of the *Luminex 100 IS Developer Workbench Guide Version 2.3* for additional information. All determinations are based on a single standard.

Quantitative analysis—determines the sample concentrations from standard curves using regression methods, such as 4P or 5P logistic curve fitting.

There are two main assay types: non-competitive (such as “capture sandwich”) and competitive. In a non-competitive assay, the slope of a concentration versus Mean Fluorescent Intensity (MFI) standard curve is a positive number. That is, low concentrations result in low MFIs and high concentrations result in high MFIs. Conversely, competitive assays generate a standard curve with a negative slope, the endpoints of which are high MFI/low concentration on the left, and low MFI/high concentrations on the right.

You may direct the system to acquire samples in replicate regardless of batch type. For qualitative batches, replicate values are averaged and the reported interpretation determined from this replicate average.

Replicates in quantitative batches are based on a standard curve that is generated by either the “Fit of all standards” or “Mean of replicates”. The chosen curve fit is defined by the assay developer when defining an assay template. The default is “Fit of all standards”. Unknown samples are calculated from the standard curve. Replicate samples are averaged to determine the reported quantitative result denoted as “AVG”.

The system can analyze only batches that it acquires using qualitative or quantitative templates. It does not analyze acquisitions using Data Collection Only or Maintenance templates.

Note: Luminex does not recommend performing Data Analysis while the Luminex 100 IS 2.3 system is performing data acquisition on another batch.

When the system analyzes batches, it displays the data in a three-tab format within the Analysis window. See Figure 5-72. The following three tabs present the batch information in greater detail:

- Standards tab—lists all tests in the batch, a regression chart for each test, and the standards or controls associated with the batch.
- Samples tab—lists background samples and all samples or unknowns acquired in the batch with either a qualitative or quantitative result.
- Errors tab—lists errors that occur during batch acquisition and data pertaining to the analyzed data, such as controls that failed.

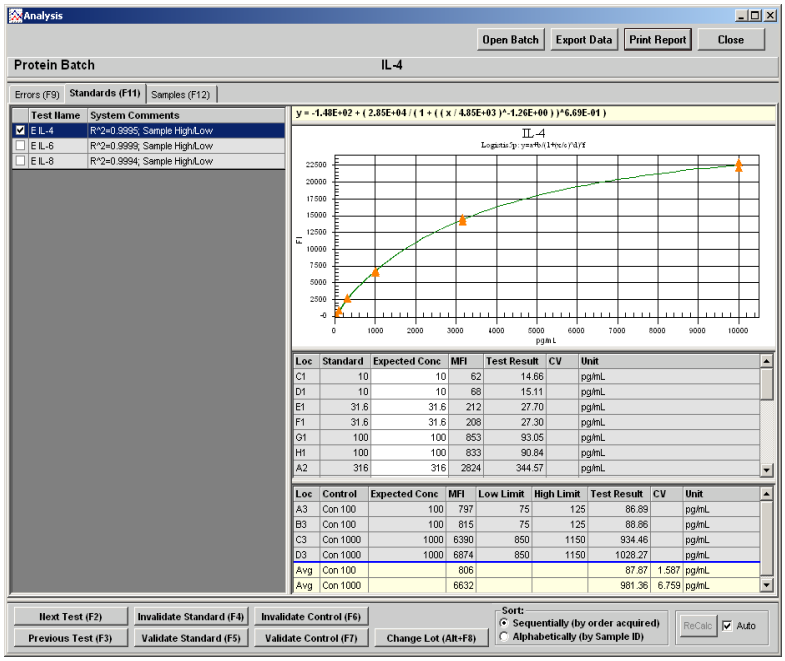


Figure 5-72 Analysis Window—Standards Tab

Enable Automatic Analysis

Note: You cannot select both Auto Export Batches and Auto-Start Analysis. The Auto Export Batches checkbox is located on the Data Export tab of the Options dialog box. Also note that Analysis and data reduction are synonymous terms.

You can configure the system to automatically start analysis (data reduction) immediately following batch acquisition. If you disable the Auto-start Analysis feature, you must select **Analysis** from the **Home** tab to analyze a batch. Note that the Auto-start Analysis feature is automatically disabled when processing a multi-batch.

- To automatically begin analysis upon completing sample acquisition:

1. On the **Tools** menu, click **Options**, and then click on the **General** tab. See Figure 5-73.

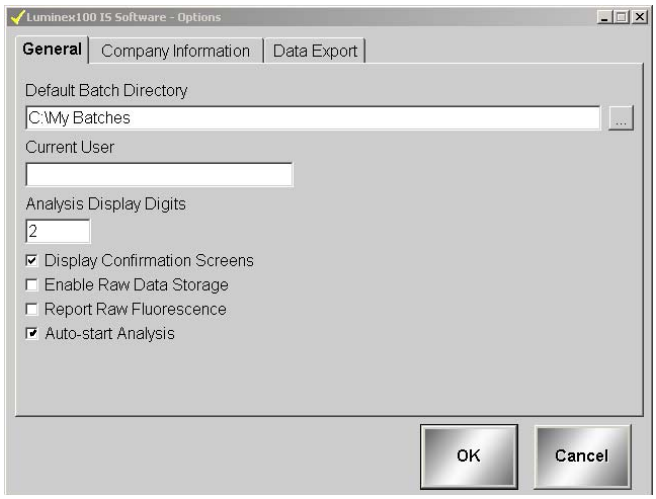


Figure 5-73 Options Dialog Box—Select Auto-start Analysis

2. On the **General** tab, click the **Auto-Start Analysis** checkbox, then click **OK**. When the system completes the batch acquisition, it will automatically begin analyzing data.

Analyze Processed Batch Data

You can analyze only processed batches. If you acquire or process batches as a multi-batch, the system lists them separately and they must be analyzed separately, and manually by the user.

All batches within a multi-batch have the multi-batch name listed under the multi-batch ID name column. This allows you to see the batches that have been processed as a multi-batch.

- To analyze data from processed batches and multi-batches:

1. On the **Home** tab, click **Analysis**. The **Open Batch** dialog box opens showing only processed batches.

2. Select a batch to analyze and click **Select**. The system loads the batch and the Analysis window displays the **Standards** tab. See Figure 5-74.

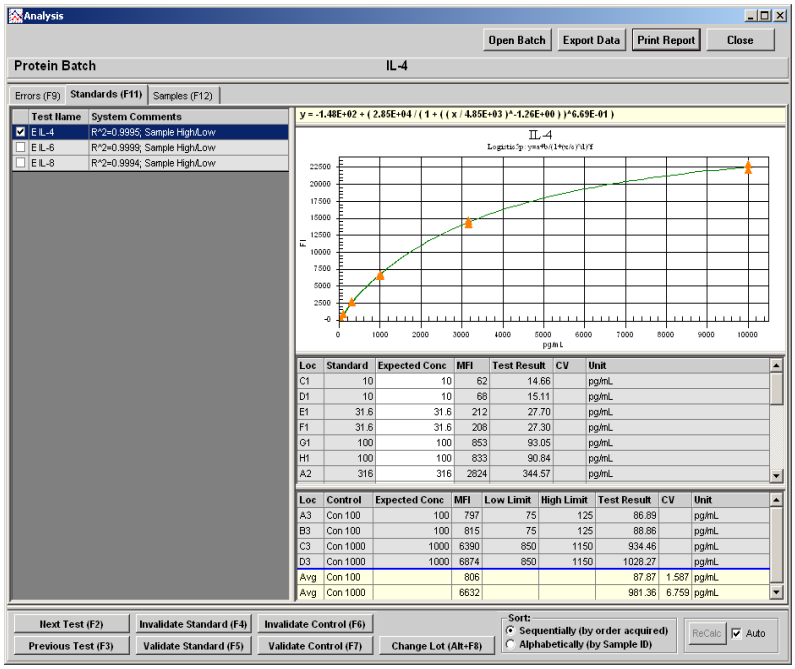


Figure 5-74 Analysis Window—Standards Tab (Data Reduction)

Four buttons appear in the upper-right corner of the Analysis window:

Open Batch. Opens an existing batch that you want to analyze.

Export Data. Exports the data to the output csv file in the batch folder. After selecting this button, there is no confirmation response.

Print Report. Prints the data interpretation report including the Standards, Controls, graph of standards, and Samples data. See “Print Data Analysis Report” on page 5-88.

Close. Closes the Analysis window.

Print Data Analysis Report

A printed batch report includes the following criteria that is applied to the batch during analysis:

- batch name and test name
- formula used
- curve fit
- standards
- controls

- samples
- graph (this is the only way to print a graph of standards)

◆ To print data analysis reports:

1. On the **Home** tab, click **Analysis**.
2. In the **Open Batch** dialog box, select the desired batch to analyze.
3. In the **Analysis** dialog box, click **Print Report**. The Data Interpretation Report displays a print preview. See Figure 5-75.
4. Select any print options along the title bar and then click the print button (printer icon).
5. At the **Microsoft Windows Print** window, select your printer, options, and click **Print**.

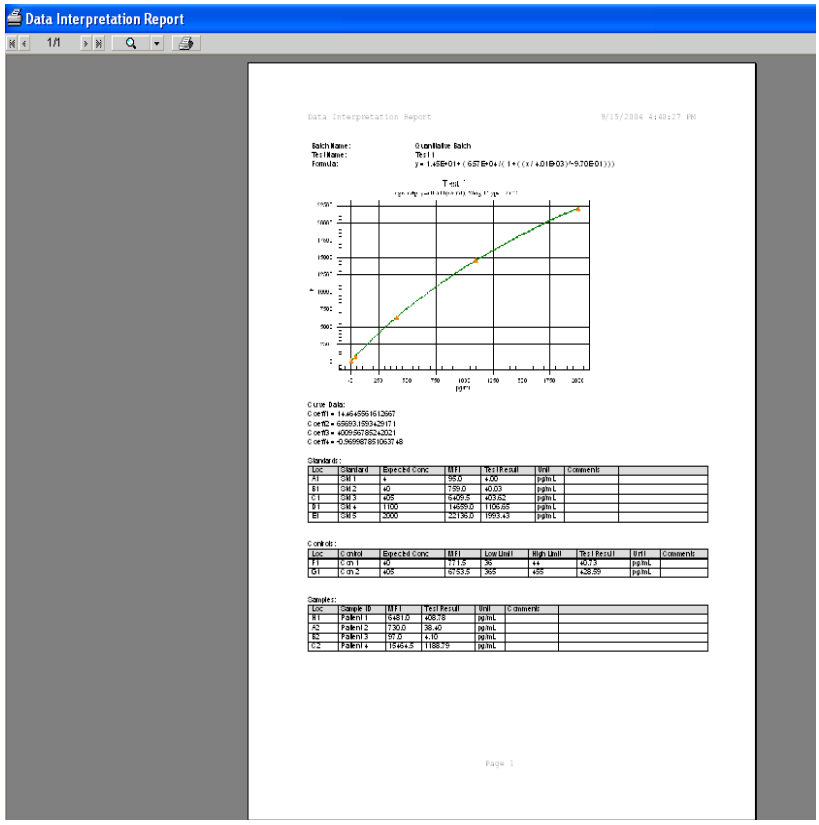


Figure 5-75 Data Interpretation Report (Print Preview)

View Detailed Test Analysis

◆ To view detailed test analysis:

1. On the **Home** tab, click **Analysis**. The **Open Batch** dialog box opens.
2. Click on the desired batch to analyze and click **Select**. The Analysis window opens showing the progress as the system opens the batch and analyzes the data. See Figure 5-74. Each test displays “Analyzing” as the system calculates.
3. On the **Standards** tab, select the test or analyte you want to view. The system displays this analyte in detail. Switch between tabs to observe the tests errors under the Errors tab and unknown results under the Samples tab.

   To view the next test in the batch click **Next Test (F2)**. To view the previous test, click **Previous Test (F3)**. You may also click on the test name in the left grid control.

Standards Tab

The Standards tab lists all the batch tests with system comments specific to each test. The detailed test information that is displayed on the three tabs of the Analysis window is determined by the test selected under the Standards tab. See Figure 5-76.

The Standards tab displays the quantitative batch’s standard curve. It displays qualitative batches as a graph plotting the assay standard. Above the graphical information, the tab displays the formula that it used to calculate batch data. Below the graphical information, the tab displays the Standards and Controls values for the selected test.

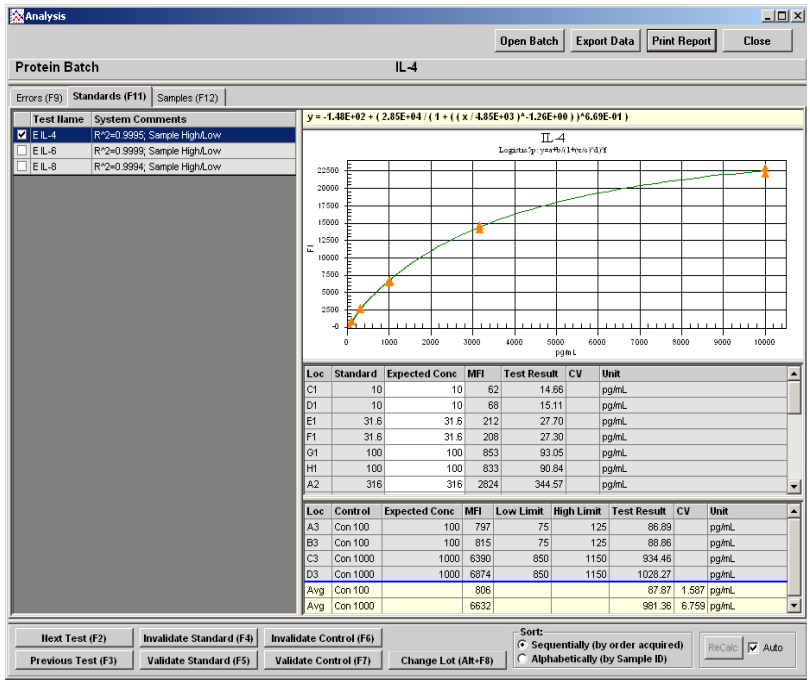


Figure 5-76 Non-Competitive Quant Analysis Window—Standards Tab

When an unknown sample or control that lies outside the standard curve MFI range is measured, the concentration cannot be determined from the MFI, and the sample's left-right position in relation to the curve is reported in the test result using a less than (<) or greater than (>) symbol next to the concentration of the limiting standard. These out-of-range samples and controls will also have a "Sample High/Low" statement in the comment column. If a sample lies within the standard curve MFI range, but the sample's MFI value does not intersect the curve, the result will be reported as "Error". A "cannot calculate inverse function" statement is added to the comments column. Note: this error condition usually occurs when a standard curve "flattens out" at the high or low end. Examples of out-of-range sample labeling for non-competitive assays are shown in Table 5-9. Figure 5-77 shows what a standard curve for a non-competitive assay should look like.

Condition	Concentration Label	MFI of Standard Referenced
Left of Curve	< min concentration standard	Lowest
Right of Curve	> max concentration standard	Highest

Table 5-9. Non-Competitive Out-Of-Range Labeling

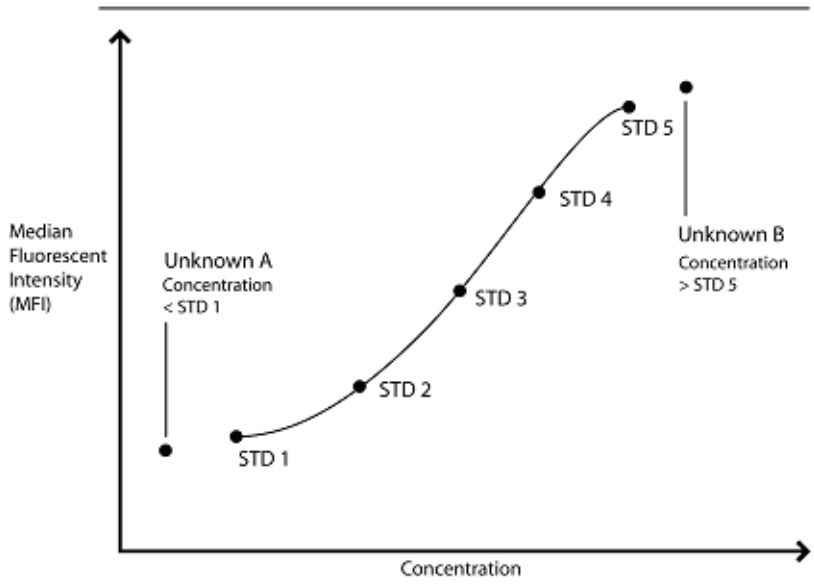


Figure 5-77 Non-Competitive Assay

Examples of out-of-range sample labeling for competitive assays are shown in Table 5-10. Figure 5-78 shows what a standard curve for a competitive assay should look like.

Condition	Concentration Label	MFI of Standard Referenced
Left of Curve	< min concentration standard	Highest
Right of Curve	> max concentration standard	Lowest

Table 5-10. Competitive Out-Of-Range Labeling

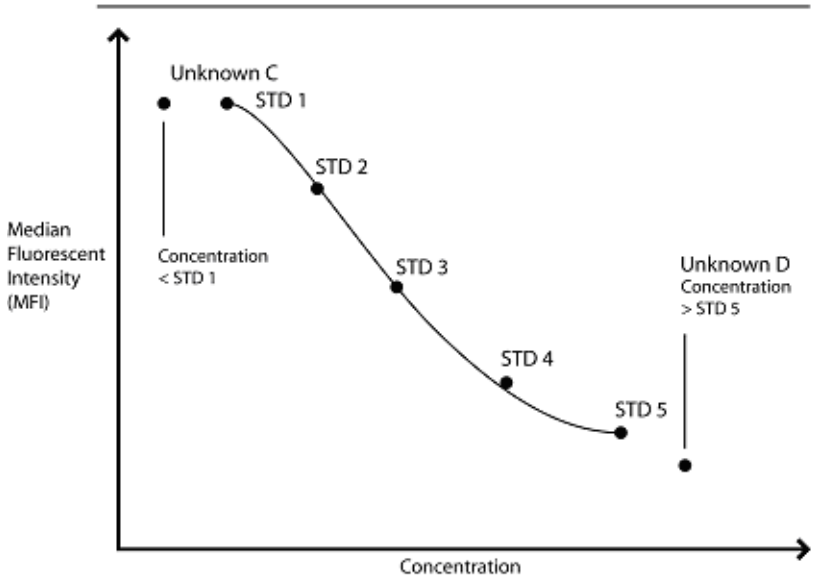


Figure 5-78 Competitive Assay

Function Keys

Eight function buttons are available on the lower portion of the Analysis window. These buttons perform tasks or functions that are relevant to the Standards tab although they appear on all three tabs of the Analysis window. The buttons are:

- Next Test (F2)
- Previous Test (F3)
- Invalidate Standard (F4)—see “Invalidate or Validate Standards and Controls” on page 5-94
- Validate Standard (F5)—see “Invalidate or Validate Standards and Controls” on page 5-94
- Invalidate Control (F6)— see “Invalidate or Validate Standards and Controls” on page 5-94
- Validate Control (F7)—see “Invalidate or Validate Standards and Controls” on page 5-94
- Change Lot (Alt + F8)—see “Change Lots” on page 5-96
- Recalc (Standards tab only)—see “Recalculation” on page 5-93

Edit lots—Click **Change Lot (Alt+F8)** to edit lots. Restrict the use of this button to correct only entry errors for standard and control lot values. To create new lots refer to “Create a New Lot” on page 5-75.

Recalculation

When you make a change, such as invalidating a standard or editing lot information, you must recalculate the affected test. The system provides two options, Automatic recalculate and manual recalculate.

The Auto checkbox (under Recalc button) at the bottom right of the Standards tab determines the option.

Figure 5-79 Recalc Button

- **Auto selection**—In the Auto selection mode changes automatically trigger the system to reanalyze the affected test. This is the default mode unless you uncheck the Auto checkbox. Uncheck Auto to use the Recalc button in the Manual recalculate mode.
- **Manual recalculate**—After making changes that require a recalculation, the system enables the Recalc button. In this mode you press the Recalc button to initiate the recalculation. Examples of Recalc scenarios include: change formula, change lot, validate/invalidate a standard/control, in-line lot changes (changing Expected Conc from the Standards grid).

Note: The Recalc button is greyed out unless you make changes that require recalculation.

Invalidate or Validate Standards and Controls

You can invalidate or validate a standard or control in either of two ways. Use the associated button on the bottom of the **Analysis** window or right-click in the desired **Expected Conc** cell.

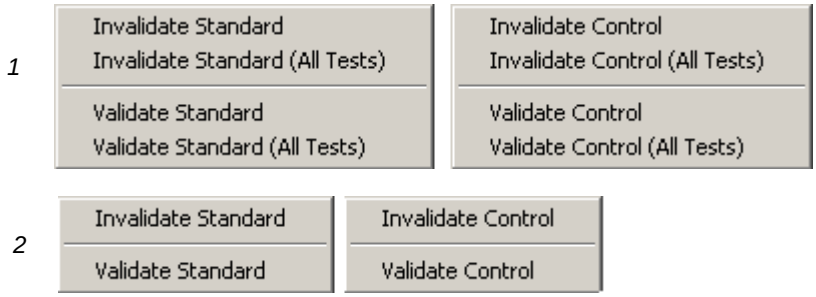
Invalidating standards—You can invalidate or remove a standard if doing so improves the curve fit. Invalidating standards greatly affects the curve fit and subsequently the sample results. However, observe caution when doing so. For further instruction on assay standard curves and the appropriateness of invalidating or removing standards, contact the assay kit manufacturer.

Invalidating controls—You can invalidate or remove a control in data analysis. However, Luminex does not recommend invalidating controls. For further instruction on assay controls and guidelines regarding accepting or rejecting control values, contact the assay kit manufacturer.

◆ To validate or invalidate a standard or control entry using the shortcut procedure:

1. Select the desired standard or control name in the Standards or Controls grid.
2. Right-click to display the related menu. See Figure 5-80. Select the desired menu item to apply. When invalidating, the **Name**

box turns red with an asterisk proceeding it. When validating, the red returns to the normal color.



1. Menu for multiple tests *2. Menu for single test*

Figure 5-80 Invalidate and Validate Shortcut Menus

3. Recalculate using Auto or the Recalc button.

◆ To validate or invalidate a standard or control entry using the Invalidate and Validate Buttons:

1. Select the desired standard or control name in the **Standards** or **Controls** grid.
2. Click one of the appropriate buttons at the bottom of the Analysis window: **Invalidate Standard (F4)**, **Validate Standard (F5)**, **Invalidate Control (F6)**, or **Validate Control (F7)**.
3. The appropriate **Standard** or **Control** dialog box opens. Figure 5-81 shows an invalidate example. If you want to invalidate or validate all tests click **Yes**. For only the single test click **No**. When invalidating, the **Name** box turns red with an asterisk proceeding it. When validating, the red returns to the normal color.
4. Click **Auto** or **Recalc** to recalculate the results.

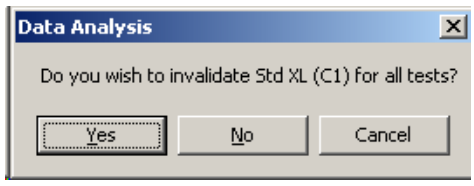


Figure 5-81 Invalidate Data Analysis Example

Expected Concentrations

The Standards tab displays an Expected Concentration column for standard and control samples. The Standards Expected Concentration column allows users to edit the standard concentrations.

You can edit controls, however, you must select the control name or **Expected Concentration** box for that control, then select the **Change Lot (Alt+F8)** button.

Note: Restrict editing lot values for use only in correcting user entry errors for standards and control lot values.

When editing standard and control lot values the system may prompt you for a new lot number. If this is the first batch you analyze using this lot number, the system allows editing without requiring a new lot name. However, if you have analyzed a previous batch using this lot, the system will require that you rename the lot if edited or modified.

Change Lots

Use this feature to edit the lot that is applied to the batch currently opened in data analysis.

- To change the lot that is applied to a batch:

1. Click **Change Lot (Alt + F8)**, located at the bottom of Analysis window, to display the **Choose Lot** dialog box. See Figure 5-82.
2. The dialog box displays a list of available standard and control lots that you can apply to a batch. Highlight the desired lot and click **OK** to apply the selected lot to the batch opened in data analysis. Figure 5-82 shows standard and control. Figure 5-83 shows standard only.

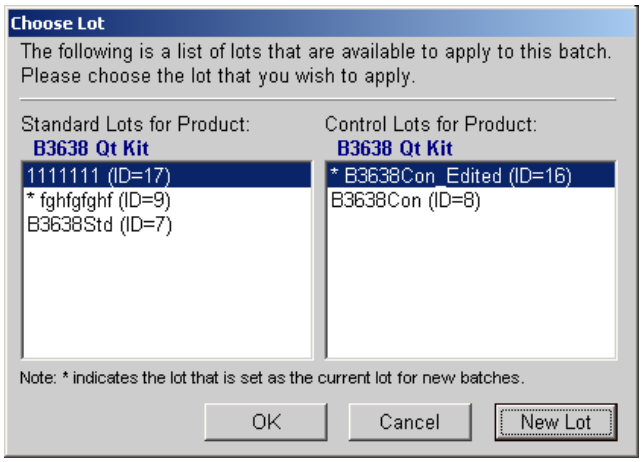


Figure 5-82 Choose Lot Dialog Box—Standard and Control

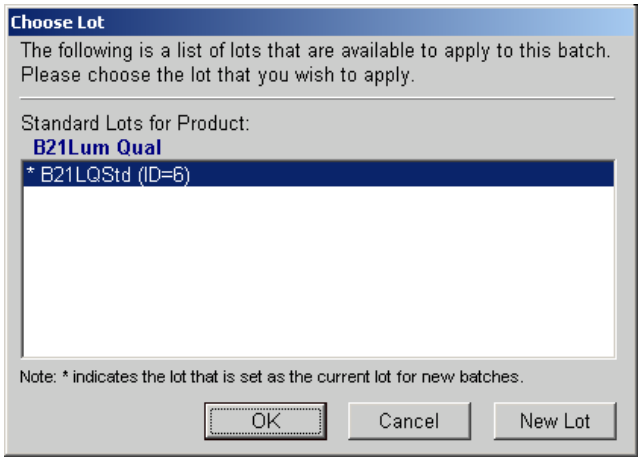


Figure 5-83 Choose Lot Dialog Box—Standard Only

3. To create a new lot from this dialog box as an alternate method, click **New Lot** and follow the steps in the **Create New Lot** procedure on “Create a New Lot” on page 5-75.

◆ To select a lot as the current lot for use with future batches:

1. Click **New Lot**.
2. In the **Update Lot Info** dialog box, select **Standard lot** or **Control lot**, then click **Save** to display the **Choose Lot** dialog box. An asterisk identifies the selected lot. See Figure 5-82.

Samples Tab

The Samples tab lists tests from your batch and displays the results for each sample.

Figure 5-84 shows a Sample tab example listing three tests. Notice that the left column displays Test IL-4, IL-6 and IL-8 with Test IL-4 selected. The Sample column on the right side shows the IL-4 sample results. Notice that the well G3 location test result is “<10” and the associated Comments column for the third sample indicates a sample out of range error “Sample High/Low” because this sample has an MFI less than the lowest standard in the standard curve for this non-competitive batch.

Note: The **Comments** column cells are editable and the information is displayed in reports.

The first sample is within the standard curve range and thus displays an unflagged test result.

The system does not flag results as normal or abnormal according to a defined range. Error flags only note samples that fall below or above the standard curve.

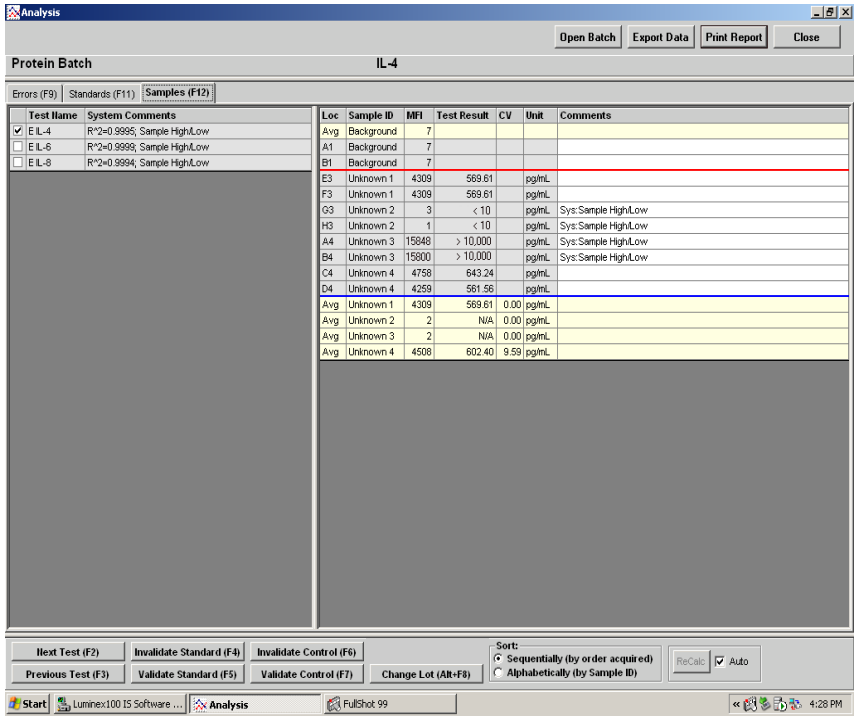


Figure 5-84 Analysis Window—Samples Tab

Replicate Averaging

Note: You predefine standard and control replicates in the template. You define unknown sample replicates in batch setup indicated by replicate Sample ID.

The data analysis function supports replicate sampling. The function calculates each sample as an individual sample, then averaged to obtain a replicate average.

- Standards tab—displays standards and controls average values.
- Samples tab—displays samples average values.

Replicate averages are displayed with AVG in the Loc (location) column.

The AVG entry appears immediately after the wells being averaged or at the end of the list depending on what you select under Sort (Sequentially or Alphabetically). See “Sample Progress Sorting” in the following section.

If the system fails to determine the results for a replicate due to an excessive skew of one of the samples, you can invalidate the out of tolerance value. Use the **Invalidate Standard (F4)** or **Invalidate Control (F6)** buttons at the bottom of the Analysis window.

However, this only fixes standards/control, not necessarily patient sample. If any of the replicate standards and/or controls are invalidated the “Avg” results reflects the average of the remaining standard and/or control replicates.

The system flags the failed sample so you may calculate the replicate set’s average without including the failed result in the equation.

Sample Progress Sorting

You can sort the batch samples on the Standards tab and Sample tab. See Figure 5-85.

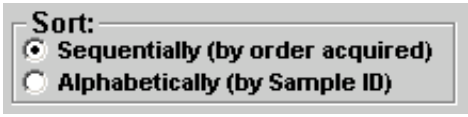


Figure 5-85 Analysis Window—Batch Sort Feature

You will find this feature helpful in viewing batches containing replicate samples. Replicate samples are defined as samples with identical sample identifications. Replicate standards, controls, and unknown samples are not always acquired in sequential wells and thus make sample viewing difficult. When viewing samples alphabetically all replicate samples are displayed together with the replicate sample’s average (AVG), then individual samples. If you view replicate batches sequentially, each sample displays in the order it was acquired, followed by a replicate average summary section.

Choose from two sorting methods:

Sequentially (by order acquired). This feature arranges sample data progress beginning with data acquired from the first sample in your batch and continues chronologically until the last sample with the AVG section at end.

Alphabetical (by sample ID). This feature arranges sample data progress alphabetically according to the sample, beginning with A to Z, then one through nine. The AVG results are listed above the individual sample results.

Errors Tab

The Errors tab displays a list of errors that occurred during acquisition. See Figure 5-86. It organizes the errors in two categories:

- System and assay errors (top section of tab)
- Sample errors (bottom section of tab)

Table 5-11 lists the errors in each category.

Table 5-11. Error Categories

System and Assay Errors	Sample Errors
• Instrument Not Calibrated • Failed Verification (system lists each failed control) • Failed Control (verifier failed) • Temperature Divergence from Calibration Temperature • Failed Curve Fit • Analysis Error • APD Temp Range Exceeded • XYP Temp Unstable • Low Voltage • High Sheath Pressure • Low Sheath Pressure • Command Timeout • Low Laser Power • Cannot Calculate Inverse Function • Failed Std in Batch	• Insufficient Bead Count • Sample High/Low • Analyzer Error • High Sheath Pressure • Low Sheath Pressure • Sample Timeout • Sample Empty • Cannot Calculate Inverse Function • Different Qualitative Results

View Detailed Error Information

◆ To view error details during acquisition:

1. In the **Analysis** window, click the **Errors** tab.
2. The top half of the screen displays system and assay related error. The name of the error and a detailed description is displayed. See Figure 5-86 and Table 5-11.
3. The bottom half of the screen displays sample related errors. The error is displayed as Test Name, Sample ID, and Errors. See Figure 5-86 and Table 5-11.

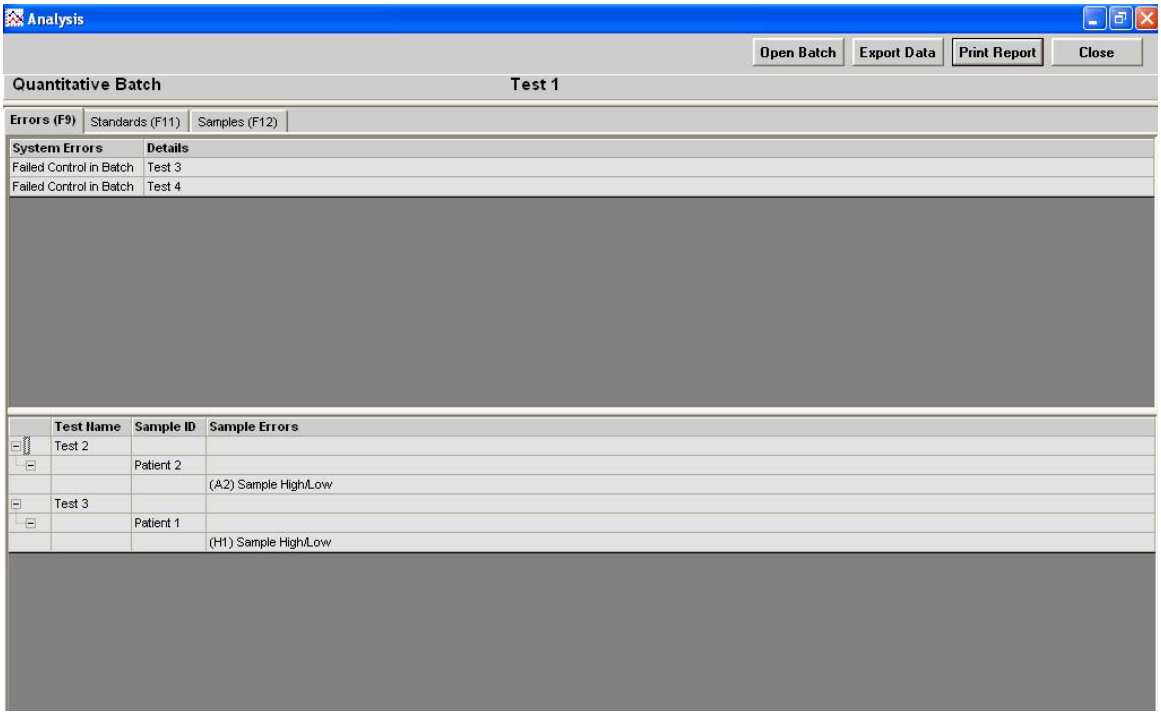


Figure 5-86 Analysis Window—Errors Tab

Customize Data Analysis Settings

You can customize how the sample data results are displayed in the analysis graph on the Standards tab. There are two options that allow you to customize the display. Use the **Customization** dialog box and the Graph Menu items; some items are available on both. You can define the general features of the graph, axis settings and increments, fonts, colors, and styles presented in the graph representing the sample data results. You also can export the analysis to a graphic, file, clipboard, and so on.

Customization Dialog Box

◆ To modify the general features of the **Standards** tab graph:

1. On the **File** menu, click **Data Analysis**.
2. Double-click the desired batch. The **Analysis** window opens displaying the **Standards** tab. See Figure 5-76.
3. Double-click anywhere within the graph to display the **Customization** dialog box. See Figure 5-87. Notice across the dialog box are five tabs: General, Axis, Font, Color, and Style. Also notice that there are six buttons along the bottom of the dialog box. They are the OK, Cancel, Apply, Original, Export, and Maximize buttons.

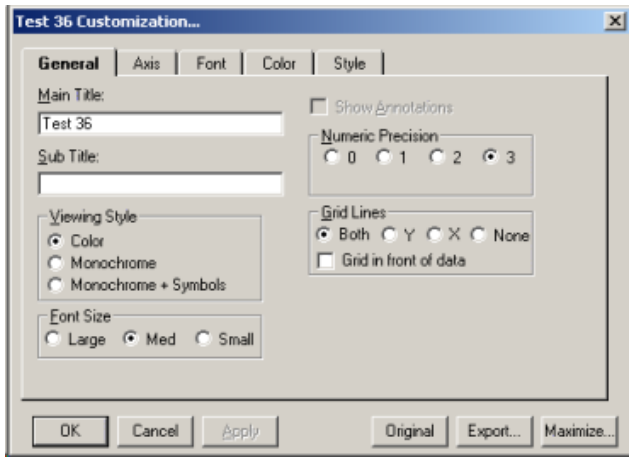


Figure 5-87 Customization Dialog Box—General Tab

Customization Dialog Box Buttons:

OK: click to update the graph's parameters with the new information and exit the Customization dialog box.

Cancel: click to abort selections and exit.

Apply: Apply is similar to the OK button, but does not close the Customization dialog box. It updates graph parameter with new information.

Original: click this button to restore the edited information to the previous or original values.

Export: click this button to export data from a Metafile or BMP graphic to a csv output file in the batch folder file, or to the clipboard. You can also export to a printer and specify the object size. Select the desired features and click Export. See Figure 5-88.

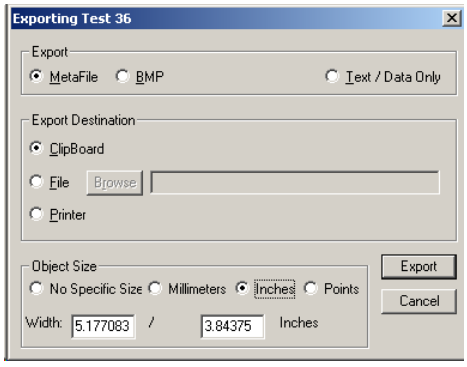


Figure 5-88 Exporting Dialog Box

Maximize: Click to maximize the graph to full screen. Restore to original size by pressing **Escape** or by clicking in the title bar.

Customization dialog box tabs:

- **General Tab**—Use this tab to define general parameters. See Figure 5-87.

  Main and Sub Titles: These edit-boxes allow you to add, edit, or delete these titles. If no title is present, you can enter one. Delete all characters from a title to remove it.

  Viewing Style: The Graph supports three viewing styles:
  Color
  Monochrome
  Monochrome with Symbols

  This customization allows you to quickly adjust the image to best suit printing on a monochrome printer. If you include fewer than four subsets in a graph, then the Monochrome setting will probably be the best choice. If four or more subsets are included in the graph, then Monochrome with Symbols will help distinguish the different subsets.

  Font Size: The Graph supports three font sizes, Large, Medium, and Small. When printing the graph, a font size of Medium or Small is suggested. On occasions the graph may automatically reduce the size of the font to produce a higher quality image.

  Show Annotations: Currently, this feature is not used. This check box allows you to remove or add the annotations from the image.

  Numeric Precision: When exporting text and data from the Export Dialog, you can define the number of decimal positions at 0, 1, 2, or 3.

  Grid Lines: The Graph can contain vertical grid lines, horizontal grid lines, both vertical and horizontal grid lines, or no grid lines. Select the appropriate radio button.

  Grid in front of data: Check this option to place the grid in front of the data graphics. Otherwise, the data graphics are drawn on top of the grid.

- **Axis Tab**—Use the Axis tab to change your X axis and Y axis values and specify whether to display them as linear or log. See Figure 5-89.

Note: If you select Log, use "Auto" or ensure that the "Min" value is greater that zero.

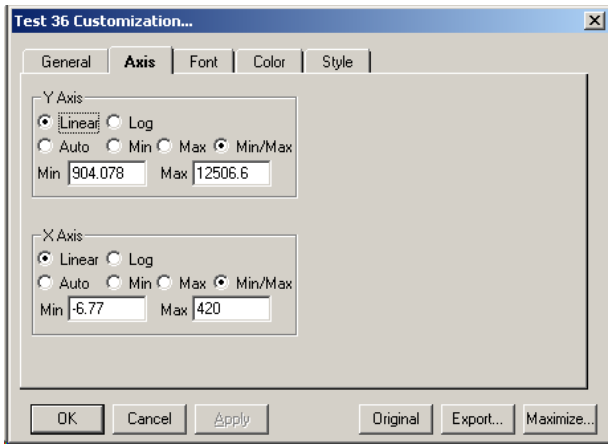


Figure 5-89 Customization Dialog Box—Axis Tab

- **Font Tab**—Use the Font tab to change the appearance of the fonts that appear in the Main Title, Sub Title, and Subset/ Point/Axis Label boxes. The bottom the of the dialog box displays a sample of the font as you select it. See Figure 5-90.

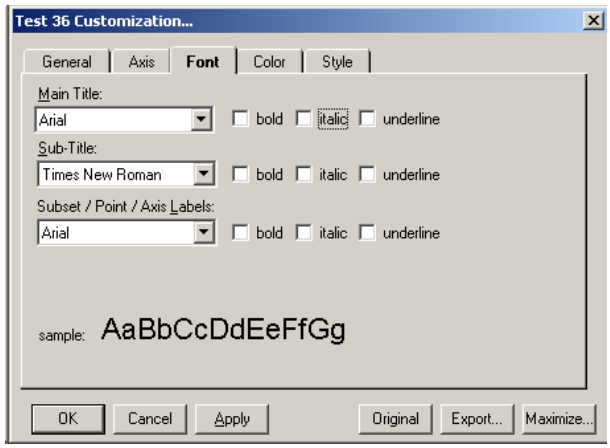


Figure 5-90 Customization Dialog Box—Font Tab

- **Color Tab**—Use the Color tab to define the various color parameters on the analysis graph. See Figure 5-91.

  Desk Foreground: this is the color that is used when placing text onto the Desk Background. It includes the main title, sub title, subset/point labels, grid numbers.

  Desk Background: this is the color that surrounds the bounding rectangle of the graph's grid. That is, the color of the border that appears behind the text labeling.

  Shadow Color: the rectangles that make up the graph's grid and table and bounded at the bottom/right edges with shadows.

To remove the shadows, choose the same color as the Desk Background.

Graph Foreground: this is the color used for the bounding rectangles of the grid, the grid-lines of the graph, and lines that are used to bound some of the plotting methods (like the bounding line around bars of the Bar Plotting Method).

Graph Background: this is the color that is used as the background color of the graph's grid.

Table Background: This is the color used in filling the table's rectangle. Currently, this feature is not used.

Table Foreground: This is the color used in bounding the table's rectangle, and for the text inside the table. Currently, this feature is not used.

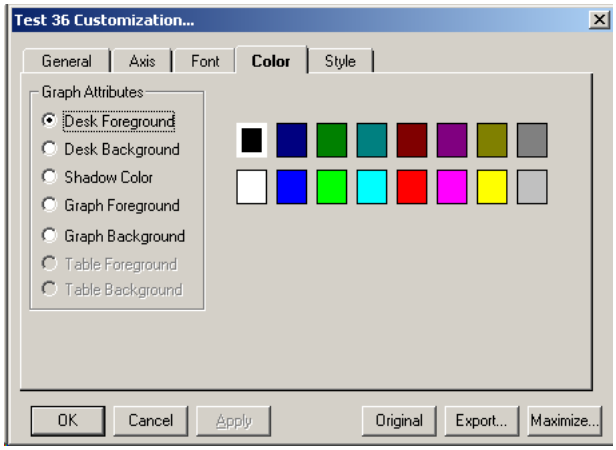


Figure 5-91 Customization Dialog Box—Color Tab

- **Style Tab**—use the Style tab for control of subset color, subset line type, and subset point type. See Figure 5-92.

◆ To edit the Style tab:

1. Select the desired subset in the Subsets list box. The corresponding color and possible line and point types are then highlighted in their respective controls.
2. To change the color, use the mouse to click an alternate color or use the keyboard arrow keys to move to adjacent colors. Adjust the subset line and point types as desired.
3. Click **OK** to update the graph's image.

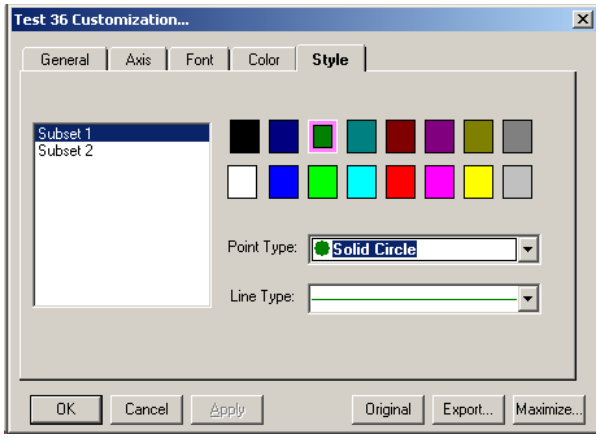


Figure 5-92 Customization Dialog Box—Style Tab

Graph Menu

Most of these menu items provide a shortcut for many of the features provided in the Customization dialog box. Refer to "Customization Dialog Box" on page 5-101 for details.

◆ To modify the general features of graph representations of the sample test result data:

1. Right-click anywhere in the graph on the **Standards** tab. The **graph** menu opens. See Figure 5-93.
2. Select the desired menu item from the list and it is immediately applied.

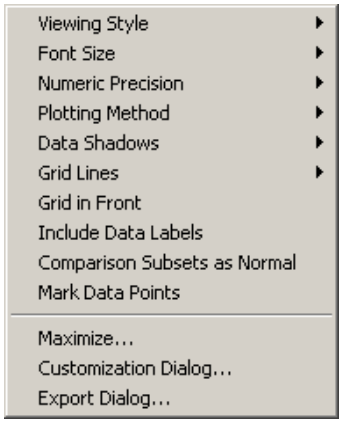


Figure 5-93 Graph Menu Items

Analyze Data Outside the IS Software

There are two ways to access the data interpretation feature from outside the Luminex 100 IS software application:

- Through the desktop Start menu

- Through Microsoft Explorer

◆ To access the **Standards** tab from Analysis using the desktop Start menu:

1. Click **Start** at the bottom left corner of the desktop.
2. From the desktop Start menu, select:
   Programs|Luminex|Luminex 100 IS|Data Interpretation Application.

   From Explore, select:
   Luminex|Luminex 100 IS|DataInterpApp.exe
3. At the **Analysis** window, click **Open Batch** to open a file for analysis.
4. Select a batch for analysis from the available batches list.
5. Click **Select**. The data for the batch you select appears in the Analysis window.

Proceed with your analysis as desired. The executable version of this analysis feature has the same functionality as that within the Luminex 100 IS 2.3 software.

◆ To access the **Standards** tab from Analysis using Microsoft Explorer:

1. Right-click on the desktop **Start** button to display the menu and click **Explore.**
2. Browse through Explorer to access the following location:
   C:\Program Files\Luminex\Luminex100IS\DataInterpApp.exe
3. Double-click the **DataInterpApp** executable file. The **Analysis** window opens.
4. Click **Open Batch** to open a file for analysis.
5. Select a batch for analysis from the available batches list, then click **Select**. The data for the batch you select appears in the **Analysis** window.

Proceed with your analysis as desired. The executable version of this analysis feature has the same functionality as that within the Luminex 100 IS software.

Data Output

You can output data by printing reports and exporting batch data.

Report Types

The Luminex 100 IS 2.3 software can format your batch or multi-batch results in a variety of report formats and provide different types of information in different types of reports. See Figure 5-94. These reports include:

- Analyte Report
- Clinical Patient Report
- Patient Summary Report
- Quality Control Report
- Maintenance Report
- Batch Summary Report
- Calibration Trend Report
- System Control Trend Report

Analyte Report This report prints some or all of the samples grouped by the test in a batch.

Clinical Patient Report This report provides a breakdown of samples according to the test analysis with that sample.

Patient Summary Report This report prints all of the test results for a patient. It may include all tests or selected tests on the report.

Quality Control Report This report is used to track the trends of assay standards and assay controls over a period of time.

Maintenance Report This report provides a history of all maintenance operations performed during the date range entered by the operator.

Batch Summary Report This report prints batch information in a sample versus test grid format. A batch summary report is useful for an assay developer to quickly reference a test result for a particular sample.

Calibration Trend Report This report provides information about all instrument calibration operations that occurred during the date range entered by the operator.

System Control Trend Report This report provides information about all verification operations that were performed during the date range entered by the operator.

Print Reports

You can print reports from within the Luminex 100 IS 2.3 software or external using a stand alone program included in the installation.

Print from within Luminex 100 IS 2.3

◆ To print a report from a batch or a specific time frame:

Install the printer before initiating the print command.

1. Click **Print Report**. The **Report Selection** dialog box opens.

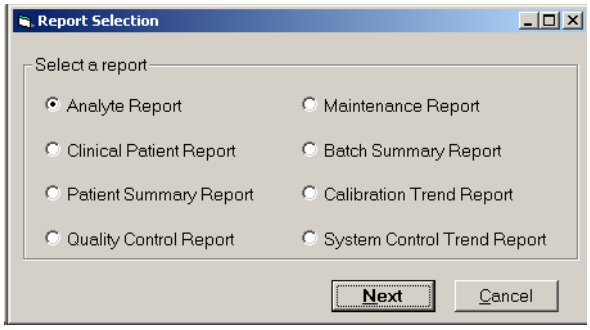


Figure 5-94 Report Selection Dialog Box

2. Select the type of report that you want to print and click **Next**. For the Analyte, Clinical Patient, and Batch Summary Reports, the **Batch Selection** dialog box opens. Select the batch to print. See Figure 5-95. For the Quality Control, Maintenance, Calibration Trend, and System Control Trend Reports, a dialog box related to the specific report opens.

Note: The system information may vary depending on the type of report that you select.

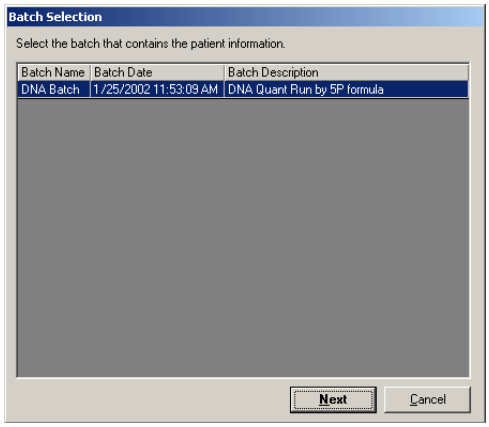


Figure 5-95 Batch Selection Dialog Box

3. Enter the information (in this example, a patient report) and click **Next**. Another information dialog box opens. Enter specific information for the type of report the system is compiling. Figure 5-96 shows a Patient Selection example.

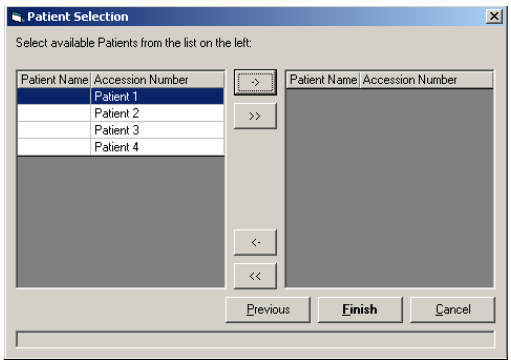


Figure 5-96 Patient Selection Dialog Box

4. Select the desired entry or click the double arrow (>>) to select all the entries.

5. Click **Finish**. A report print preview appears using the information you entered. See Figure 5-97. You may have more than one dialog box in which to enter information.

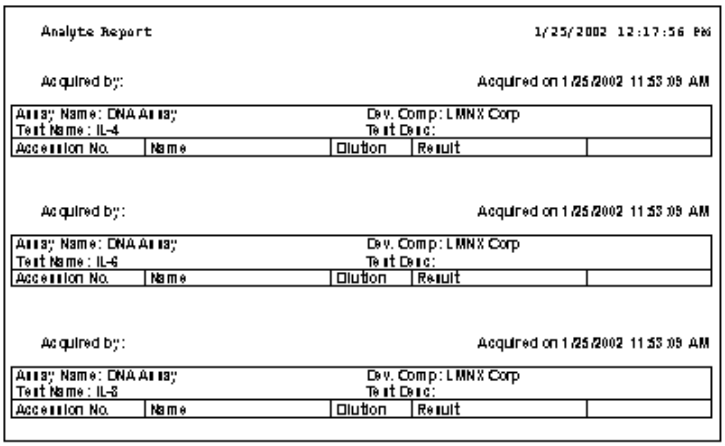


Figure 5-97 Report Print Preview Dialog Box

6. Click **Print Report** to print the report.

7. The **Print** dialog box opens. Select the desired parameters and click Print.

Print Using External Program

There are two ways to print reports from outside of the Luminex 100 IS 2.3 software.

◆ To print a report using the desktop Start menu or Explore:

1. Click **Start** at the bottom left corner of the desktop.

2. From the desktop Start menu, select: Programs|Luminex|Luminex 100 IS|Report Application. The **Report Selection** dialog box opens. See Figure 5-94.

3. Continue as explained in the "Print from within Luminex 100 IS 2.3" on page 5-109.

◆ To print reports using Explorer:

1. Use Explorer to navigate to: Luminex\Luminex100IS\ ReportApp.exe.

2. Double-click **ReportApp.exe**. The **Report Selection** dialog box opens. See Figure 5-94.

3. Continue as explained in the "Print from within Luminex 100 IS 2.3" on page 5-109.

Export Batch Data

◆ To export batch data:

1. On the **File** menu, , click **Export Batch Data**. The **Open Batch** dialog box opens. See Figure 5-98.

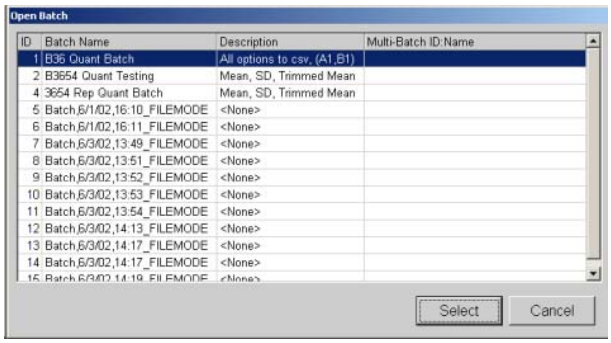


Figure 5-98 Open Batch Dialog Box—Select Batch

2. Select the desired batch to export.

3. Click **Select**. The system exports the information. The **Export Batch** dialog box opens showing the name and location of the exported data file. Click **OK**. See Figure 5-99.

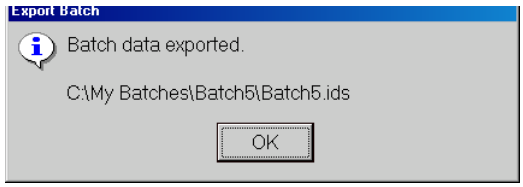


Figure 5-99 Batch Data Exported Dialog Box

Database Management

You manage the system database by backing up and deleting saved data and files.

The system stores data results for instrument calibrators, instrument controls, assay calibrators, and assay controls. It records acquisition and maintenance data in real-time to minimize data loss in case of system failure. Each batch file records the date and time, command cancellation (if applicable), and voltages used for the commands performed during the batch.

Back Up the Database

Back up the system database following the schedule set by your laboratory. Your laboratory may require you to back the system up weekly, daily, or after you complete each batch.

If your laboratory has no schedule for database backups, the system does inform you when your database approaches its size limit. You should back up the database according to a periodic schedule.

◆ To back up the database:

1. On the **Tools** menu, click **Database Backup**. The **Backup Database To** dialog box opens

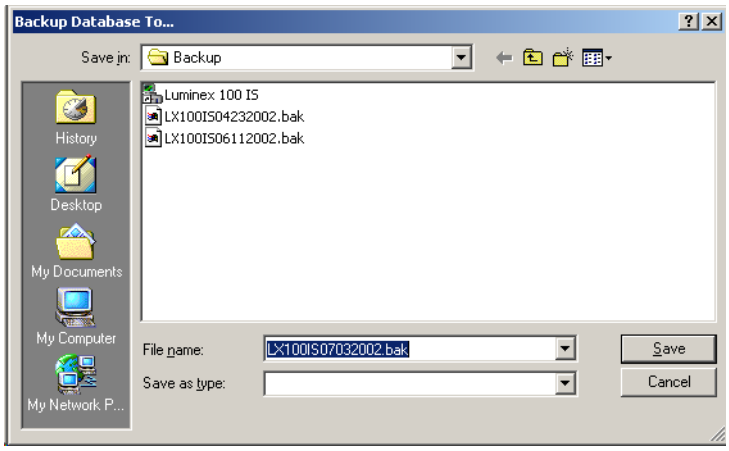


Figure 5-100 Backup Database To Dialog Box

2. Choose the file name and location of the database that you want to back up.

3. Click **Save**. The **LX100 IS Database Backup** dialog box opens informing you the backup is in progress to the specified location. See Figure 5-101.

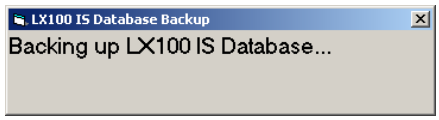


Figure 5-101 Database Backup Dialog Box

Erase the Database Data

You can erase sample information from the database at any time. You will see a warning when the database is 80% full (approximately 200 MB free of a two GB hard drive limit). This provides advanced warning to erase database information.

When the database is 98% full, sample acquisition is prevented. System calibration and control information is not affected when you erase sample information. The system also does not affect standard and control information while erasing data from the database.

◆ To erase information from the database:

1. On the **Tools** menu, click **Erase Database**. The **Choose Date** calendar opens. See Figure 5-102.
2. Choose the day after the last day of the database entries that you want to erase. For example, all data prior to January 16 are erased. January 16 is kept.

Figure 5-102 Choose Date Calendar

3. Click **OK**. The **Delete Database Entries** dialog box opens and warns that you are about to delete database records.

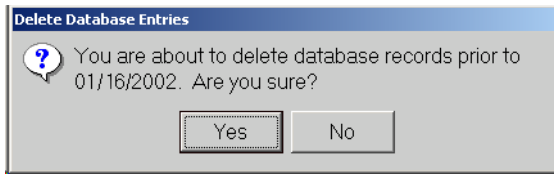


Figure 5-103 Delete Database Entries Dialog Box

4. If you are sure you want to delete this data, click **Yes**. The system deletes all events stored before the day you select.

Restore Database Data

Restore the database from a previously saved database.

◆ To restore information to the database:

1. On the **Tools** menu, click **Database Restore**. The **Restore Database** dialog box warns you that the Luminex 100 IS software will shut down after restoring the database. See Figure 5-104.

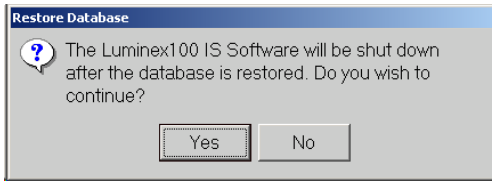


Figure 5-104 Restore Database Dialog Box

2. Click **Yes** to continue to restore a database.

3. From the **Restore Database From** dialog box, select a database backup file to restore and click **Open**. See Figure 5-105. The system restores the previously saved database. Notice that the files are organized by date (month-day-year).

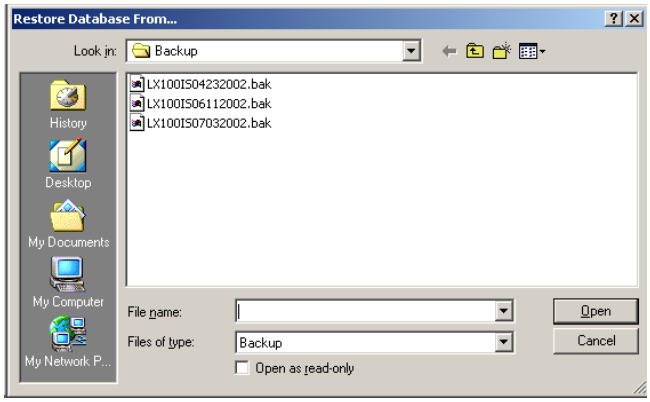


Figure 5-105 Restore Database From Dialog Box

A **Database Restored** dialog box opens the next time you start up the system. The dialog box prompts you to verify that the lot information for CAL 1, CAL2, CON1, and CON2 reagents are correct. See Figure 5-106.

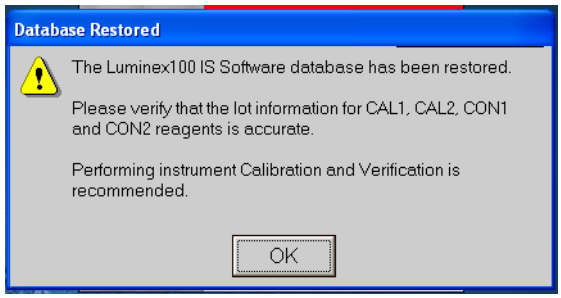


Figure 5-106 Database Restored Dialog Box

4. Click **OK** to verify that the lot information is accurate.

Cleanup Utility

Use the Cleanup Utility to:

- Perform a disk cleanup
- Delete the Message Log Directory
- Delete the Batch Directory

◆ To display the Cleanup Utility dialog box:

1. On the **Tools** menu, click **Cleanup**. The **Cleanup Utility** dialog box opens.
2. Continue with the desired following section, Disk Cleanup, Delete MsgLog, or Delete Batch Directory.

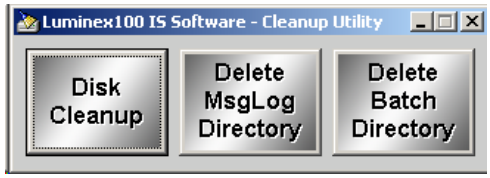


Figure 5-107 Cleanup Utility Dialog Box

Disk Cleanup

This is a shortcut to the Windows Disk Cleanup feature.

◆ To perform a disk cleanup:

1. In the **Cleanup Utility** dialog box, click **Disk Cleanup**. See Figure 5-107.

2. In the **Select Drive** dialog box, select the desired drive and click **OK**. See Figure 5-108. The **Disk Cleanup** dialog box opens showing it is calculating progress. This can take several minutes. See Figure 5-109.

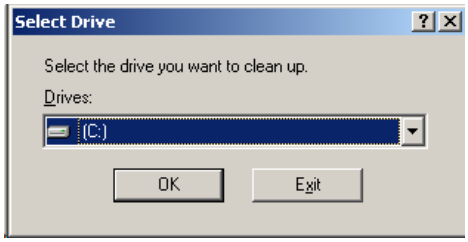


Figure 5-108 Select Drive Dialog Box

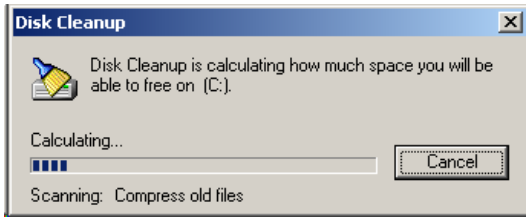


Figure 5-109 Disk Cleanup Dialog Box

3. When Windows finishes calculating the cleanup it displays the **Disk Cleanup for** dialog box. See Figure 5-110. Check or uncheck the desired files to delete and click **OK**. Windows deletes the files and closes the dialog box.

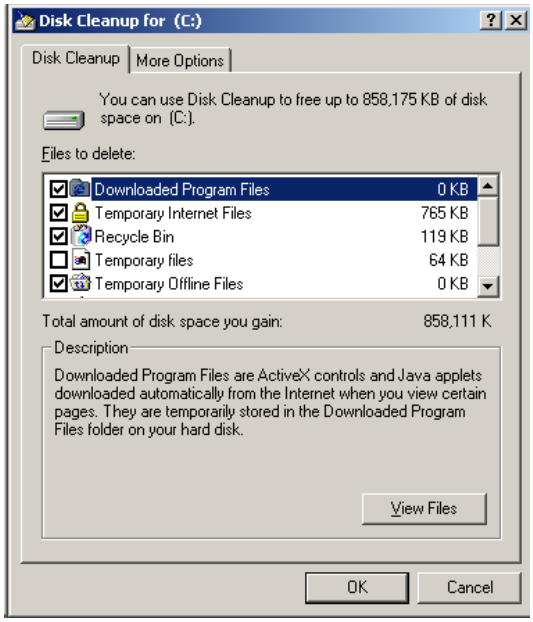


Figure 5-110 Disk Cleanup for (Selected Drive)

Delete MsgLog Directory

- To delete the Message Log directory:

1. In the **Cleanup Utility** dialog box, click **Delete MsgLog Directory**. See Figure 5-107.
2. In the **Cleanup Utility** confirmation dialog box, click **Yes** to delete the Message Log. See Figure 5-111.

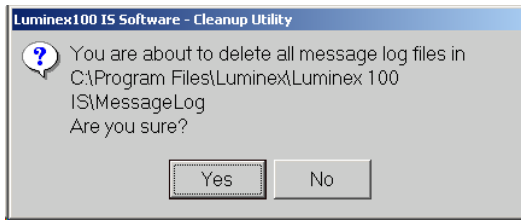


Figure 5-111 Cleanup Utility Confirmation Dialog Box

Delete Batch Directory

- To delete the batch folders:

1. In the **Cleanup Utility** dialog box, click **Delete Batch Directory**. See Figure 5-107.
2. In the **Cleanup Utility** confirmation box click **Yes** to delete all the batch folders See Figure 5-112. All the folders under C:\My Batches are deleted. The C:\My Batches folder remains.

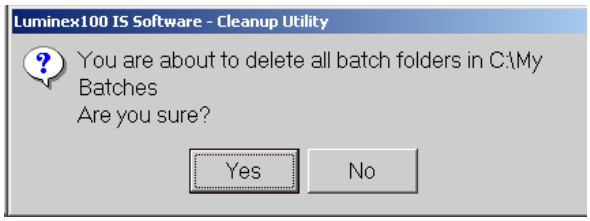


Figure 5-112 Cleanup Utility Confirmation Dialog Box

Help Menu

The system has an array of help files regarding various Luminex 100 IS features and capabilities. You may find these topics by searching the contents of books and topics or by searching an alphabetic listing of the topics and books.

Online Help Structure

Topic Topics provide information and details regarding software features, system capabilities, and any number of related material.

Book Books usually contain a group of topics. These topics are grouped together because they discuss similar or related topics.

Hyperlink Hyperlinks provide instant access to another topic or subtopic with related information to the linked subject or term.

Use Online Help

Open System Help

◆ To open the system's online help:

1. On the **Help** menu, click **Contents**.
2. In the Help dialog box, scroll through the contents and select the desired topic. Also, consider the index to locate information.
3. Double-click the help topic that you want to view. A topical dialog box opens with information on that topic.

About the Device

◆ To display device information about the Luminex 100 analyzer, Luminex XYP instrument, and the Luminex LXR SDK:

1. On the **Help** menu, click **About the Device**. The About the Luminex 100 & Luminex XYP Devices dialog box shows information that may be helpful when contacting Luminex Technical Support. See Figure 5-113.

Figure 5-113 About Device Dialog Box

2. Click **OK** to close the dialog box.

About the Luminex 100 IS 2.3 Software

◆ To display information about the system software:

On the **Help** menu, click **About the Software.** The **About Luminex 100 IS Software** dialog box shows information about

the system software. This includes software version, build number, and the system copyright information. See Figure 5-114. Click **OK** to close the dialog box.

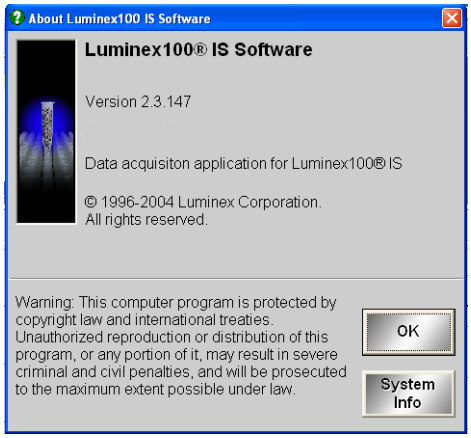


Figure 5-114 About Luminex 100 IS Software Dialog Box

System Information

- To display system information:

1. On the **Help** menu, click **About the Software**. **The About Luminex 100 IS Software** dialog box opens that displays software information.
2. Click **System Info**. The **System Information** dialog box opens. See Figure 5-115.
3. Click **X** in the top-right corner to close the dialog box.
4. Click **OK** on the About Luminex 100 IS Software dialog box.

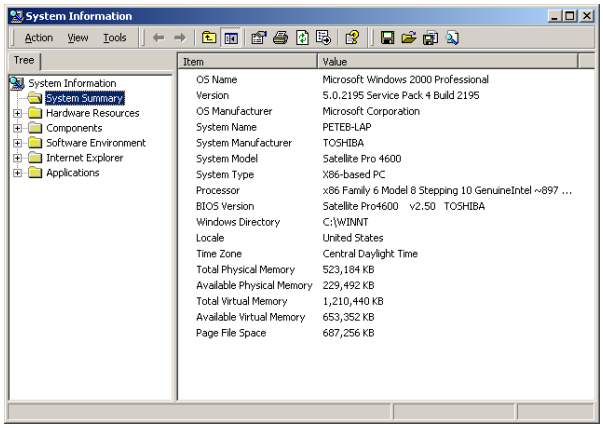


Figure 5-115 System Information Dialog Box

Shut Down the Analyzer

Luminex recommends sanitizing with 10% to 20% household bleach as part of your daily shutdown routine after biohazard contact. Sanitizing uses the Luminex XYP reservoir to accommodate the amount of fluid necessary to sanitize the Luminex 100 analyzer. After sanitizing, perform a soak command to soak the probe in distilled water to prevent crystal formation in the Luminex XYP sample probe.

◆ To shutdown the Luminex 100 analyzer:

1. On the **Maintenance** tab, click **Sanitize**. A confirmation dialog box opens prompting you to place sanitize solution (10% to 20% bleach) in the XYP reservoir.
2. Click **Eject/Retract**. The plate holder ejects.
3. Place the solution in the XYP reservoir and click **Eject/Retract** to retract the plate holder.
4. Click **OK** to continue. Wait until the Sanitize command completes before initiating another command.
5. Perform two **Washes** with distilled water.
6. Click **Soak** to fill the sample probe with distilled water to prevent sheath fluid crystals from forming in the sample probe. A confirmation dialog box opens. See Figure 5-116.

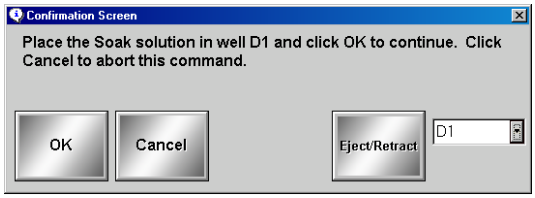


Figure 5-116 Confirmation Screen Dialog Box

7. Click the **drop-down arrow** to the right of the Eject/Retract button. An image of the microtiter plate and reservoir appears in the plate holder. See Figure 5-117.

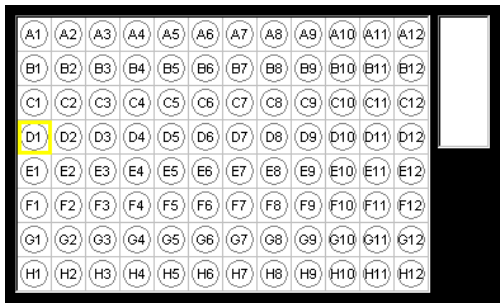


Figure 5-117 Microtiter Plate Image For Location Selection

Note: The system may show a default location from which to draw fluid. In this case, the microtiter plate shows that well with a yellow line outlining the well.

8. Select a well location to draw fluid from using the image of the microtiter plate and reservoir, then click **Eject/Retract**. The plate holder ejects.
9. Place 200µL of distilled water into selected well location.
10. Click **OK** to continue. The Message Log on the Diagnostics tab indicates that the command started. The Device Activity box on the Status Bar indicates that the system is soaking. Wait until the soak command completes before initiating another command. Upon completion, the microtiter plate representation shows a green well with a check mark to indicate the command's success or a red well with an X mark to indicate the command's failure.

Exit Luminex 100 IS 2.3 Software

When you exit the system a confirmation dialog box prompts you to verify that you really want to exit the system.

- To exit the system:

  On the **File** menu, click **Exit**, then click **Yes**.

6 Maintenance and Cleaning

To ensure accurate test results, properly clean and maintain the Luminex 100 IS system. Read and follow all instructions in this section. For your convenience, a maintenance log form is included at the end of this chapter.

> **Warning**: When analyzing potentially infectious biological samples on the Luminex 100 analyzer, follow standard laboratory safety practices. These safety precautions should also be taken when cleaning or maintaining the analyzer.

Do not remove the analyzer cover under any circumstances!

Daily Maintenance

If the system is powered on, but idle for more than four hours, click the **Maintenance** tab. Click **Warmup.** Wait 30 minutes for the Luminex 100 analyzer and the optics system to warm up.

Before Running Samples

◆ Before you run samples:

1. Turn the Luminex 100 analyzer on. The system begins warming automatically.
2. Verify the levels of sheath fluid and waste fluid.
3. When the system is warmed up, click **Prime** to prime the analyzer, then click **OK**.
4. Click **Alcohol Flush**. A confirmation dialog box opens. Click **Eject/Retract** to eject the Luminex XYP instrument tray. Place at least 1.2 mL of 70% isopropanol or 70% ethanol in the reservoir. Click **OK**.

5. Click **Wash.** In the confirmation dialog box, click on the drop-down arrow located to the right of the Eject/Retract button to choose the desired location. Click **Eject/Retract**. The Luminex XYP instrument tray ejects. Place sheath fluid in the selected well or reservoir on the plate. Click **OK**. Perform this step twice.
6. Check that the Luminex XYP instrument sample probe has been vertically aligned for the plate used in the kit.

After Running Samples

◆ After running samples:

Refer to “Maintenance Commands” on page 5-19 for detailed Sanitize and Soak command operation.

1. **Sanitize** with a 10% to 20% household bleach solution.
2. Run two **Wash** cycles with distilled water.
3. **Soak** with distilled water. Wait until the soak completes.
4. If desired, turn off the Luminex 100 analyzer.

Routine Tasks

Sheath and Waste Fluids

Replace the sheath fluid and empty the waste container as required. You must manually monitor waste container levels. The Run Batch tab displays a warning when you need to refill (or replace) the sheath fluid container. See Figure 6-1.

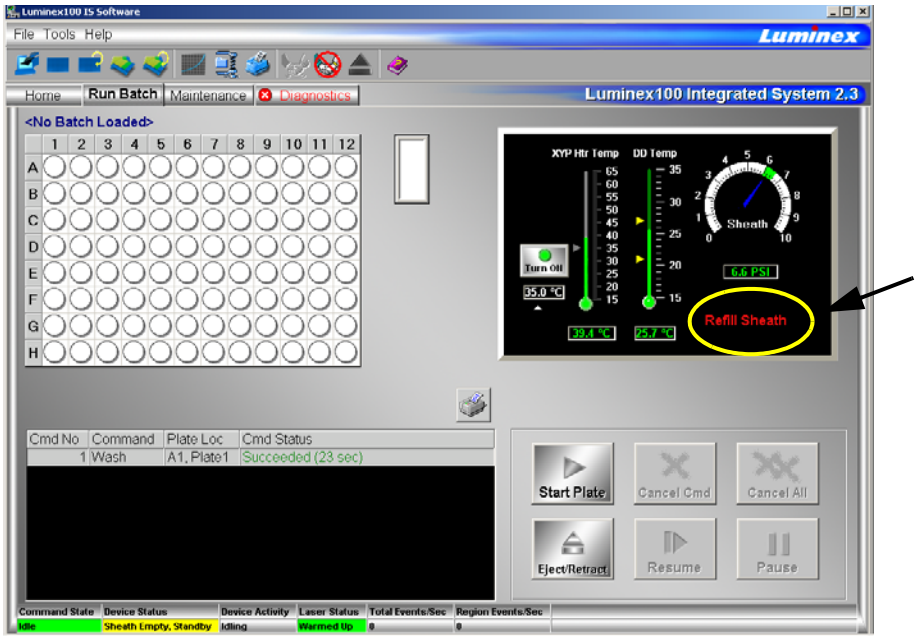


Figure 6-1 Refill Sheath Fluid Warning (Circled in Photo)

Refill the Sheath Fluid Container

◆ To refill the sheath fluid container:

1. Release system pressure by removing the lid from the sheath fluid container.
2. Replace the sheath fluid box with a new box or refill the sheath fluid container.

Empty the Waste Container

◆ To empty the waste container:

1. Disconnect the waste container from the Luminex 100 analyzer.
2. Discard the waste from the waste container by appropriate means.
3. Reconnect the waste container to the Luminex 100 analyzer and replace the cap.

   Any time the sheath container is disconnected from the Luminex 100 analyzer, you must remove air from the sample lines by priming.

   If the sheath container ever runs dry, prime the system at least twice until the air is removed from the system.

Note: There is NO warning of a high waste volume. Empty the waste container each time you fill the sheath container.

Weekly

Visual Inspection

Open all of the Luminex 100 analyzer doors and visually inspect for leaks, corrosion, and other signs of improper function. Check all visible tubing connections. Check the Luminex XYP instrument air intake filter for buildup of dust. Check the SD system and its connection for leaks. If you see a leak, turn off the power to the Luminex SD system and contact Luminex Corporation.

Run Self-Diagnostics

Run Self-Diagnostics on a weekly basis to check system integrity. On the **Maintenance** tab, click **Self Diag**. The system performs self-diagnostic tests. The results display on the **Diagnostics** tab.

Clean Sample Probe

Clean the sample probe. Remove the sample probe and sonicate the narrow end for 2-3 minutes.Use a syringe to flush the sample probe with distilled water from the narrow end out through the larger end. Replace the sample probe and readjust the sample probe height for the plates you are using with the Luminex XYP instrument.

Flush the System

Run 3 backflushes, 3 drains, 2 alcohol flushes and 3 washes with distilled water.

Monthly

Clean the Sample Probe

Danger: Be sure that the system is not performing an operation when you remove the sample probe.

Caution: The Luminex XYP instrument sample probe should slide up easily while removing it from the sample arm. If you feel resistance, do not force the probe up. Contact Luminex Technical Support.

◆ To clean the sample probe:

1. Remove the sample probe as follows. First, unsnap the light housing located above the probe. Then, unscrew the Cheminert fitting on top of the probe completely. Next, gently grasp the probe and push up. Remove the probe out of the top of the sample arm.

2. Clean the sample probe using a bath sonicator or using a 10 mL syringe. If you are using a bath sonicator, place the smaller end of the sample probe in the bath sonicator for 2 to 5 minutes. If you are using a syringe, force 10% to 20% bleach through the larger end of the sample probe.
3. Replace the sample probe and adjust the vertical height. You should adjust the vertical height anytime the probe is removed.
4. **Alcohol Flush** the system with 70% isopropanol or 70% ethanol.

Clean Exterior Surfaces

◆ To clean exterior surfaces, follow these steps:

1. Disconnect the system from ac power by turning off the power switches and unplugging the Luminex 100 analyzer, the Luminex XYP instrument, and the Luminex SD system.
2. Wipe all exterior surfaces with mild detergent, then a 10% to 20% bleach solution, and finally with plain distilled water.
3. Open both doors of the analyzer and clean all accessible surfaces with detergent followed by a 10% to 20% bleach solution and then plain distilled water.
4. Dry the sheet metal surfaces to prevent corrosion.
5. Plug in and power on the Luminex 100 analyzer, the Luminex XYP instrument, and the Luminex SD system.
6. Calibrate the system as outline in “Calibration and Verification” on page 5-28.

Calibration and System Controls

Run calibration and system controls at least once a month during routine use and:

- following installation
- if the system is moved
- if a part is replaced
- if the delta calibration temperature shown on the system monitor (located on the Diagnostics tab) is more than ±3 degrees.

Each step usually takes less than one minute. **You must run xMAP controls after each calibration**. See “Run System xMAP Controls” on page 5-31.

Every Six Months

Luminex 100 Analyzer Air Intake Filter

Note: Hold on to the tubing!
Do not allow the tubing to fall inside the the analyzer.

◆ To replace the analyzer air intake filter:

1. Disconnect the Luminex 100 analyzer from ac power by turning off the power switch on the rear of the analyzer, then unplugging the power cord from the wall source.
2. On the back of the Luminex 100 analyzer, in the upper left corner, remove the screw at the top of the panel and open the panel door.
3. Grasp the tubing and pull the filter 3 to 4 inches from the unit. See Figure 6-2.

Figure 6-2 Grasping the Tubing

4. Remove the filter with one hand, and hold the tubing with the other hand.
5. Connect a new filter to the tubing and position the filter inside the panel.
6. Reattach the panel door to the unit.
7. Plug in and power on the Luminex 100 analyzer.

Luminex XYP Instrument Air Intake Filter

◆ To replace the XYP instrument air intake filter:

1. Disconnect the Luminex XYP instrument from ac power by turning off the power switch on the rear of the Luminex XYP instrument, then unplugging the Luminex XYP instrument power cord from the wall source.

2. On the back of the Luminex XYP instrument, to the left side, gently remove the screen from the Luminex XYP instrument filter. **Note: Do not remove the screws**. See Figure 6-3.

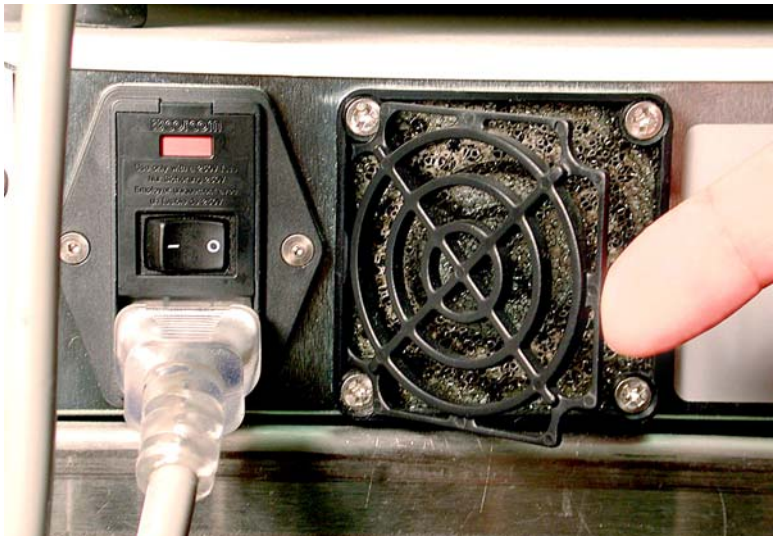


Figure 6-3 Removing the Screen

3. Replace the filter and replace the screen. See Figure 6-4.

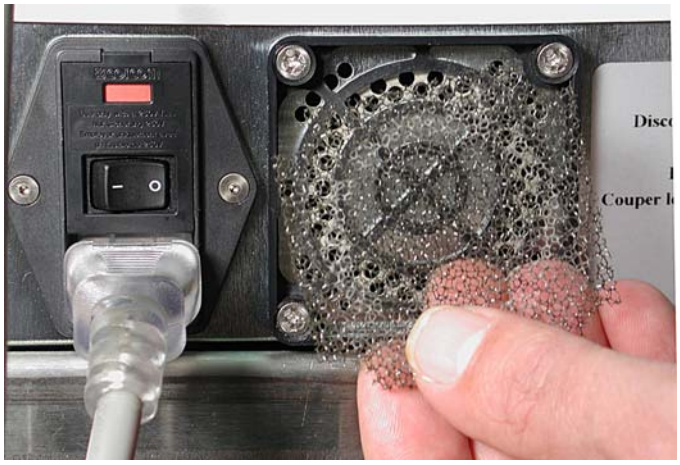


Figure 6-4 Removing and Replacing the Filter

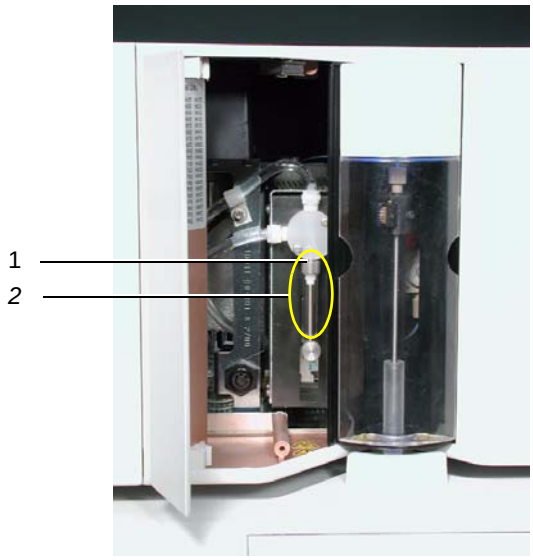
4. Plug in and turn on Luminex XYP instrument power.

Syringe Seal

◆ To replace the syringe plunger seal:

Danger: The syringe arm does not deactivate when changing the plunger; injury could result if the system is not unplugged.

1. Disconnect the Luminex 100 analyzer from ac power by turning off the power switch on the rear of the analyzer, then unplugging the power cord from the wall source.
2. Open the center-most door on the front of the Luminex 100 analyzer.
3. Locate the syringe (a glass cylinder with a metal rod). See Figure 6-5.



1. Syringe Seal 2. Syringe

Figure 6-5 Syringe and Syringe Seal

4. Unscrew the knob on the syringe arm (at the bottom of the syringe), and forcefully push the syringe arm down.
5. Unscrew the syringe from the top of its housing.
6. Pull the plunger out of the syringe.
7. Remove and replace the plunger seal. Keep the black “O” ring.
8. Return the plunger to the syringe.
9. Screw the syringe back into its housing.
10. Return the syringe arm to its original position.

11. Hand-tighten the screw on the syringe arm.
12. Plug in the power cord and turn the Luminex 100 analyzer power on.
13. Prime the system twice, watching for any leaks in the syringe area.
14. When the prime finishes, close the center door.

Luminex 100 Analyzer Ventilation Filter

◆ To clean the Luminex 100 analyzer ventilation filter:

1. Disconnect the Luminex 100 analyzer from ac power by turning off the power switch on the rear of the analyzer, then unplug the analyzer power cord from the wall source.
2. While facing the Luminex 100 analyzer, push your index finger up under the right side of the analyzer (in the space between the Luminex 100 analyzer and the Luminex XYP instrument). When you feel the filter, push the filter toward the left of the analyzer. See Figure 6-6.
3. Remove the filter from the left side of the Luminex 100 analyzer.

Figure 6-6 Luminex 100 Analyzer Ventilation Filter

4. Clean the filter with a vacuum or with distilled water. Stand the filter upright to air dry.
5. Re-install it with the arrows facing up. The filter should click into place.
6. Plug in and turn on the Luminex 100 analyzer power.

Annually

Sheath Filter

◆ To change the Luminex 100 analyzer sheath filter:

1. Disconnect the Luminex 100 analyzer from ac power by turning off the power switch on the rear of the analyzer, then unplugging the analyzer power cord from the wall source.
2. Disconnect the sheath fluid tubing before changing the filter.
3. Open the left door on the Luminex 100 analyzer. Disconnect the filter by pushing down on the metal clamps on each connection. See Figure 6-7.

Figure 6-7 Sheath Filter

4. Connect the new sheath filter, matching up the color-coded fittings. The arrow on the sheath filter should be pointing up.
5. Reconnect the sheath fluid tubing.
6. Plug in and power on the Luminex 100 analyzer.
7. Close the left analyzer door.
8. Prime twice.

As required

Fuses

Danger: To avoid serious injury or death by electric shock, you must turn off the system and unplug it from the wall outlet.

◆ To replace the fuses in either the Luminex 100 analyzer or the Luminex XYP instrument:

1. Turn off the power switch on the rear of the analyzer or instrument, then unplug the instrument power cord from the wall source. Remove the power cord from the analyzer or instrument.
2. With a small, flathead screwdriver, open the module door on the lower left corner of the back of the analyzer or instrument. See Figure 6-8.

Figure 6-8 Opening the Module Door

3. Remove the red cartridge (use a flathead screwdriver).
4. Check both fuses for damage.
5. Replace damaged fuses with the type specified on the sticker to the right of the power input module.
6. Replace the module door.
7. Plug in and power on the analyzer or instrument.

Luminex 100 IS Maintenance Log Month(s): _____Year:_____

Procedure: Use this form to record information over a four-week period. Fill in the month(s) and year above. Fill in the dates in the first line of the table. For each item listed at the left, enter your initials under each date that you perform the item.

Note: Follow your standard laboratory safety practices when cleaning or maintaining the system. **Do not remove the instrument cover** under any circumstances.

Dates																													
Daily maintenance																													
Startup	Initials: (for each item listed at the left, fill in your initials under each date that you perform the item)																												
Laser warmup																													
Check sheath fluid																													
Check waste level																													
Tighten sheath cap																													
Alcohol Flush (70% isopropanol or 70% ethanol)																													
Wash twice (sheath fluid or distilled water)																													
Shut down	Initials: (for each item listed at the left, fill in your initials under each date that you perform the item)																												
Sanitize (10% to 20% household bleach solution)																													
Wash twice (water)																													
Loosen sheath cap																													
Turn system off (optional)																													
Weekly																													
Visual inspection	Date/Initials:							Date/Initials:								Date/Initials:								Date/Initials:					
Monthly																													
Clean sample probe	Date/Initials:																												
Wipe exterior surfaces	Date/Initials:																												
Calibrate and verify	Date/Initials:																												
Every six months																													
Replace air intake filter, analyzer	Date/Initials:																												
Replace air intake filter, XYP	Date/Initials:																												
Replace syringe plunger seal, or syringe	Date/Initials:																												
Check analyzer ventilation filter	Date/Initials:																												
Yearly																													
Replace sheath filter	Date/Initials:																												
As required																													
Replace fuses	Date/Initials:																												
Comments:																													

7 Troubleshooting

Troubleshooting the Luminex 100 IS System

Troubleshooting procedures help users isolate, identify, and remedy problems with the Luminex 100 analyzer and Luminex XYP. This chapter does not troubleshoot problems with the PC. For help with PC problems, please call Dell Technical Support at 800-624-9896.

To troubleshoot a problem, select a general symptom. Next, identify the possible problem and remedy it with one of the solutions listed.

This troubleshooting chapter supplies information for the following topics:

- Power Supply Problems
- Communication
- Pressurization
- Fluid Leaks
- Sample Probe
- Calibration Problems
- Acquisition Problems
- Bead Detail Irregularities
- Error Messages
- Printing Errors
- Verification

You can find answers to frequently asked questions (FAQs) on our website: http://luminexcorp.custhelp.com.

Luminex Technical Support is available to users in the U.S. and Canada by calling 1-877-785-BEAD (-2323) between 7:00 a.m. and 7:00 p.m. Central Time, Monday through Friday. Users outside of the U.S., Canada and Europe can call us at +1-512-381-4397 between

7:00 a.m. and 7:00 p.m. Central Time, Monday through Friday. Inquiries may also be sent by email to support@luminexcorp.com.

Users in Europe can call us at +31-162408333 between 8:30 and 5:30, Central European Time, Monday through Friday. Email inquiries in Europe can be sent to supporteurope@luminexcorp.com

Power Supply Problems

Power supply problems often involve a blown fuse, faulty electronic component, or even something as simple as a disconnected cable. Use extreme care when you replace a fuse.

Symptom	Possible problem	Solution
Analyzer will not turn on, or XYP will not turn on.	The power cord is disconnected.	Verify that the power cord is Plugged in.
	No voltage is coming from the electrical outlet.	Verify that the electrical outlet is operational.
	The power supply is faulty.	Contact Technical Support.
	A fuse has burned out.	See page 6-11 for instructions on changing fuses.
Fuses continue to open (blow).	A component has a short circuit.	Contact Technical Support.

Communication

The communication problems described in this section involve the links between the data system (PC and Luminex Data Collector software) and the Luminex 100 analyzer and XYP instrument. This section does not address communication issues with other peripheral devices.

- The term “Communication” refers to:
- The transfer of data between the PC and the analyzer.
- The current status of the analyzer and XYP instrument.
- Instrument readbacks.
- Instrument control, sample acquisition, session uploading, and start, stop and pause features.

Symptom	Possible problem	Solution
PC cannot initialize communication with analyzer.	The communication cable is unplugged, or plugged into the wrong port.	Check the communications cable connections.

	The XYP or the LX 100 power is not turned on.	Turn off the PC and then turn on the LX100, XYP, and then the PC.

Pressurization

Normal air and sheath pressure readings vary between 6-9 psi while the compressor runs. If the system pressure is out of range, your sample acquisition will fail or return poor results.

Symptom	Possible problem	Solution
Pressurization fails or pressure is too low.	The sheath and waste lines are not fully connected.	Make sure the lines between the sheath and waste bottles and the analyzer are fully connected.
	An air leak is present in the sheath bottle.	Remove and retighten the sheath bottle cap.
	The sheath or waste bottle fittings are cracked.	Inspect the fittings to be sure they form a tight seal.
	There is a leak in the system.	Check for system leaks.
	The compressor does not engage.	Run a Prime command. If you do not hear the compressor turn on, call Technical Support.
	The Cheminert Fitting is loose.	Ensure that the fitting connects tightly above the sample probe, below the blue light.
	Fluid leaks in the system.	See Fluid Leak on page 7-4.
	The sheath bottle has an air leak.	Disconnect the sheath and waste bottle connections from the analyzer. Run a Prime Command. If pressure builds, remove and retighten the sheath fluid bottle cap, then reconnect fluid lines to the analyzer. If pressurization fails again, replace the sheath bottle.

	Problem internal to the instrument.	Determine if the problem is with the analyzer or the SD or bottles by disconnecting the sheath line from the analyzer and running a prime. Check the air pressure on the Diagnostic tab. If air pressure builds, the problem is with the SD or sheath fluid bottle.
Pressure too High	The sheath bottle is overfilled.	Ensure that the sheath bottle is not filled above the fill line.
	Regulator not adjusted properly.	If using bottles, open the center door on the Luminex analyzer. Use a screwdriver to adjust the regulator to fit in the center of the green region on the Run Batch tab. If you are using an SD, see Appendix D of this manual.

Fluid Leaks

Fluid leaks can result in poor pressurization and failed sample acquisition.

Symptom	Possible problem	Solution
Pressure too low	The sample probe is clogged.	Clean the sample probe. See page 6-4.
	The syringe seal leaks.	Replace the syringe seal. See page 6-8
	The syringe valve leaks	Hand-tighten the syringe connection (silver knob) on the syringe valve. Run a Prime command. If leaks continue, call Technical Support.
Large amount of fluid pooled around instrument.	Fittings or fluid lines are damaged.	Call Technical Support.
Fluid dripping from the sample probe.	The sample probe is clogged.	Clean the sample probe. See page 6-4.
	The sample three-way valve is faulty.	Contact Technical Support.

Fluid is leaking from the front of the analyzer.	The syringe seal leaks.	Replace the syringe seal. See page 6-8.
	The syringe valve leaks.	Hand-tighten the syringe connection. (silver knob) to the white syringe valve. Run a Prime. If leaks continue, contact Technical Support.

Sample Probe

Problems with the sample probe can lead to fluid leaks and pressurization problems, as well as inhibit sample acquisition.

Symptom	Possible problem	Solution
Sample probe leak	The sample probe is clogged.	Clean the sample probe. See page 6-4.
Sample arm is stuck in the up position.	The system isn't properly pressurized.	Ensure that the sample probe is not clogged and there are no leaks in the syringe seal or syringe valve.

Sample arm stuck in the down position.	The sample probe height is too low, or the path to the well is blocked.	DO NOT turn off the Luminex XYP instrument. 1. Remove the blue light housing from the Luminex 100. 2. Unscrew the tubing connector that connects the sample tube to the top of the sample arm. The system monitor changes from "Busy" to "Running" and sample acquisition continues. Click Cancel to make adjustments before continuing with the rest of the samples. 3. If the sample arm still does not raise, save all the data that has been collected to this point. Turn off the analyzer, but keep the XYP instrument on. 4. Exit the Luminex IS Software. 5. Turn the analyzer back on and restart the software. 6. Replace the sample tubing and blue light. Adjust the sample arm. 7. Run a calibration with DI water to reset the sample probe optical switch.
Sample arm does not go down smoothly.	The 96-well plate is incorrectly seated in the XYP instrument.	Adjust the 96-well plate.
	The 96-well plate is warped.	Inspect the 96-well plate. Replace it if it is warped.
	The sample arm is misaligned.	Readjust the sample arm horizontal alignment.

	The analyzer is misaligned with the XYP instrument.	Reposition the Luminex 100 analyzer on top of the Luminex XYP instrument so that the holes match up correctly. The alignment guide should tighten and loosen fairly easily if the instruments are aligned correctly. Continue to square the instruments until the guide loosens and tightens easily.
	The sample probe is bent.	Remove the sample probe from the Luminex 100 analyzer. Roll it on a flat surface. If it does not roll smoothly, replace it with a new sample probe.

Calibration and Control Problems

Symptom	Possible problem	Solution
Calibration is slow or fails.	The calibration microspheres are not fully suspended.	Vortex the calibration vials to resuspend the microspheres.
	Wrong calibration lot number or target values are entered in **Update CAL Targets** dialog box.	Verify that the correct lot number and target values are used. See page 5-28 for further information.
	The system calibrators are in the wrong well on the plate.	Verify that you placed the calibrator into the correct well. See page 5-28.
	Not enough calibrator microspheres added to the well.	Make sure that you use four or five drops of calibrator microspheres to the well.
	Calibrator lot is expired.	Use a new bottle of calibrator beads.
	The sample probe height is incorrect.	Adjust the sample probe height. See page B-8.
	The sample probe is clogged.	Clean the sample probe. See page 6-4.

	There is a partial clog in the system.	Clean the sample probe. See page 6-4. Run 3 backflushes, 3 drains, 2 alcohol flushes, and 3 washes with distilled water.
	There is air in the system.	Run a prime and alcohol flush.
	Possible problem with the laser.	View the calibration trend report. Check for dramatic changes in temperature, sheath pressure, or voltages. If any of these situations are evident on the report, Contact Technical Support.
Zero events collected during calibration.	There is a problem with fluid levels.	Check the fluid levels in the sheath and waste containers. Verify that both bottles are tightly connected to the instrument. Check that the waste bottle cap is vented.
	Laser-related issue.	Verify fluid is moving through the system by performing a wash. A wash function will cause fluid to go out to waste in five distinctive spurts. If there s not fluid going to waste, clean the sample probe (see page 6-4). Run 3 backflushes, 3 drains, 2 alcohol flushes, and 3 washes with distilled water. If the issue does not resolve, contact Technical Support.
Analyzer fails Controls.	The control microspheres are not fully suspended.	Vortex the control vials to resuspend the microspheres.
	Wrong control lot number or target values are entered in **Update CON Targets** dialog box.	Verify that the correct lot number and target values are used. See page 5-28 for further information.
	The system calibrators are in the wrong well on the plate.	Verify that you placed the control microspheres into the correct well. See page 5-28.

	Not enough control microspheres added to the well.	Make sure that you use at least four or five drops of control microspheres to the well.
	Control lot is expired.	Use a new bottle of control microspheres.
	The sample probe height is incorrect.	Adjust the sample probe height. See page B-8.
	The sample probe is clogged.	Clean the sample probe. See page 6-4.
	There is air in the system.	Run a prime and alcohol flush.
	Possible problem with the lasers.	View the system control trend report. Check for dramatic changes in temperature, sheath pressure, or voltages. If any of these situations are evident on the report, Contact Technical Support.

Acquisition Problems

Symptom	Possible problem	Solution
Acquisition fails or slows.	The air pressure is out of range.	See Pressurization on page 7-3.
	The sample probe is not vertically aligned	Adjust the sample probe height. See page B-8.
	The sample probe is clogged.	Clean the sample probe. See page 6-4.
	The sheath bottle has a leaky seal.	Make sure that the sheath bottle lid is tightened. Remove and replace the sheath bottle lid.
	The sheath or waste lines are not fully connected.	Check to make sure all tubes are tightly connected.
	The Calibration microspheres have expired.	Replace old microspheres with a fresh lot.

	The calibration lot number selected in setup is incorrect.	Enter the correct calibration lot number in the **Update CAL Targets** dialog box.
	Target values for chosen calibration lot number are incorrect.	Enter the correct target values in the **Update CAL Targets** dialog box.
	The wrong wells are selected in the Setup XY tab.	Ensure that the correct wells are selected in the **Run Batch** tab.
Slow or unsuccessful sample acquisition	The air pressure is out of range.	See Pressurization on page 7-3.
	The sample probe is clogged.	Clean the sample probe. See page 6-4.
	The sample probe is not vertically aligned.	Adjust the sample probe height. See page B-8.
	Air is present in the system.	Run three Prime commands, then resume sample acquisition.
	The acquisition volume is set too high.	Set the acquisition volume to at least 25 µL less than the actual volume in your wells. This setting lets the analyzer acquire sample more efficiently with less chance of acquiring air.
	The xMAP microspheres are not fully suspended.	Vortex or pipette your samples up and down to ensure that the beads are present in the solution.
	You are using photobleached microspheres.	Replace photobleached microspheres with a fresh lot of microspheres.
	There is an insufficient number of beads in the sample.	Ensure that there are 2000-5000 beads per set per well.

Bead Detail Irregularities

Use these tools to assist in diagnosing system and kit-related problems:

- system calibrators
- system controls
- assay standards
- assay controls

- error messages

Review reports routinely to detect trends.

Use system xMAP control microspheres to check the success of the system calibration and for troubleshooting purposes. If there is a problem with your kit results, xMAP controls can help determine if the problem is analyzer related. If Calibration and Controls are successful, contact the kit manufacturer.

A normal bead detail display is shown below. It depicts a tight bead population within a white region.

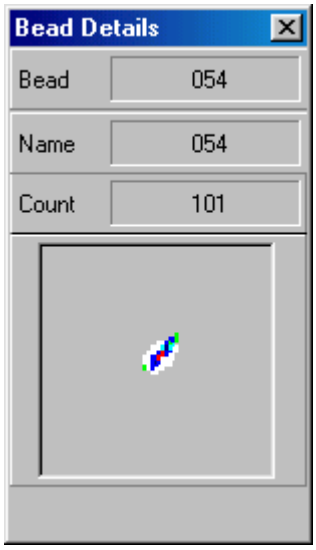


Figure 7-1 Normal Bead Detail

The histogram for the bead detail above looks like this:

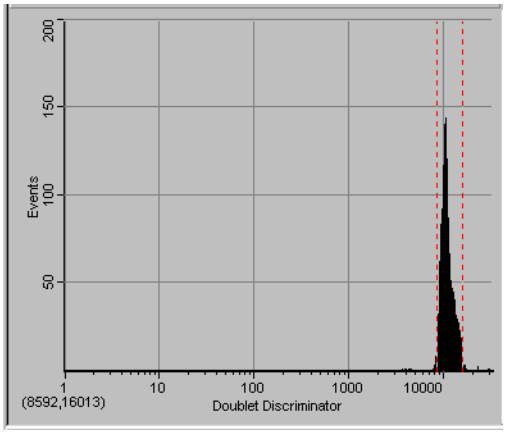
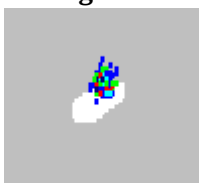
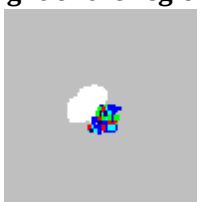
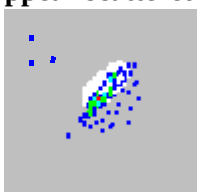
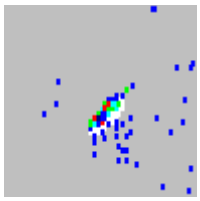
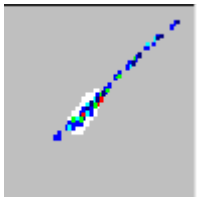
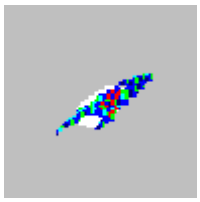
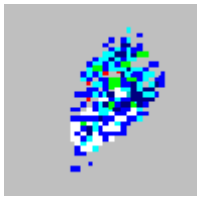


Figure 7-2 Normal Histogram

Symptom	Possible problem	Solution
Calibration microspheres classify too high. 	You may be using photobleached calibration microspheres.	Replace the microspheres with a fresh batch. To avoid photobleaching, protect your microspheres from light.
xMAP microspheres hit the lower right of the region. 	You may be using photobleached xMAP microspheres.	Replace microspheres with a fresh batch. To avoid photobleaching, protect your microspheres from light.
Beads appear scattered. 	There is air in the system.	Verify sample probe height. Run 2-3 Alcohol Flush commands.
	The sheath fluid is empty.	Make sure there is sheath fluid in the sheath container. Prime the system until all air is out of the system.
Microspheres appear as a long diagonal line. 	The xMAP microspheres have agglutinated.	Add additional detergent to the assay buffer. For example, add .02% to 0.1% Tween-20, Triton® X100, or SDS.
	The solvent is incompatible.	View a list of incompatible solvents at the Luminex Technical Support website - http://luminexcorp.custhelp.com. If the solvent you are using is listed, switch solvents.

	You are using incompatible sheath fluid.	Use only Luminex sheath fluid in the Luminex 100 analyzer. Other fluids may damage your analyzer.

Error States

The following error states display on the Status Bar on the Run Batch tab when an error occurs during system operation.

Error Message	Possible problem	Solution
Disconnected	The software hasn't made initial connection.	On the toolbar, click **Connect**; wait for the status to change.
	The communication cables are not connected.	Remove and reconnect the cable connections.
		Close the software application and reopen it.
		Close the software application, then turn off the Luminex system. Power on the system and check the status.
Refill Sheath	Sheath fluid is low.	Refill the sheath container, then click **Resume**.
Running: Sheath Empty	Sheath fluid is empty.	Replace or fill the sheath fluid container with sheath fluid. Run two Prime commands.

System Error Messages

There are two types of error messages: system error messages, and sample error messages.

System error messages are displayed in three places:

- the Message Log on the Diagnostics Tab
- the message log located in the Windows message log folder
- the Errors tab

Error Message	Possible problem	Solution
Unknown Diagnostic Error	Unknown/varied	Record the error code number and message. Contact Luminex Technical Support.
XYP Instrument Heater Stability Range Exceeded	The heater block temperature is not hitting the target value.	
Low Voltage Detected	Possible laser failure.	Turn off the analyzer, XYP, and PC, then turn them back on. Calibrate and verify the system. If the error message occurs again, contact Luminex Technical Support.
Runtime Sheath Pressure out of Limits (Too High)	The sheath fluid pressure is too high.	Ensure that the sheath fluid container is at the same level as the analyzer. On systems with a Luminex Sheath Delivery system, ensure that the sheath fluid pressure reading is equal to the original ready by adjusting the regulator as outlined in “Install the SD System” on page B-10. Calibrate and verify the system.
Runtime Sheath Pressure Out of Limits (Too Low)	There is a pressurization problem with the sheath fluid.	See Pressurization on page 7-3.
Low Laser Power Detected	The system isn’t sufficiently warmed up.	Warm up the system. This takes approximately 30 minutes. Calibrate and verify the system.
	Possible Laser Failure	Open the calibration trend report for L100CAL2 and record the last three reporter voltages. Contact Luminex Technical Support with this information.

Command Encountered Time Out Error	The current command failed.	Check the system to verify that it is warmed up and that there are no pressurization problems. Repeat the command. If the command continues to time out, contact Technical Support.
Instrument Not Calibrated	The instrument is out of calibration.	Calibrate the instrument.

Sample Error Messages

Sample error messages occur when there is a problem with sample acquisition. These errors can display on the Diagnostics tab in the Message Log, in Reports, or on the Errors tab in a batch analysis.

Message	Possible problem	Solution
Insufficient Bead Count	There are not enough beads seen to meet the minimum requested.	Ensure there are 2000-5000 beads per set per well. Ensure proper beads are selected. Adjust sample probe height. Resuspend beads in the wells. Check for clogs.
Temperature Divergence from Calibration Temperature	You are running the system at an ambient temperature that is out of range of the temperature at which the system was initially calibrated.	Calibrate and verify the system. If this message still appears after calibration, contact Technical Support.
Failed Control in Batch.	One or more of the assay controls are not within the expected range.	Verify that you selected the correct template. Verify that the correct assay lot number and concentration values were selected and entered correctly.

		Verify that the system is functioning properly by running the system controls. If the system controls pass, contact the kit manufacturer.
Failed Curve Fit	The calculation could not occur for the assay standards for data interpretation.	Verify that you selected the correct template. Verify that the correct control lot number and target values were selected and entered correctly. Verify that the system is functioning properly by running the system controls. If the system controls pass, contact the kit manufacturer.
Sample High or Low	The results do not fall within the highest and lowest standards. The wrong control lot number or target values are selected.	Verify that you selected the correct template. Verify that the correct control lot number and target values were selected and entered correctly. Verify that the system is functioning properly by running the system controls. If the sample is noted as High, dilute the sample following the kit manufacturer's suggestions. If the sample is noted as Low, vortex the sample to ensure homogeneity.
Sample Timed Out	The samples are concentrated. Not enough sample loaded into the well. Sample probe is clogged.	Verify that the samples are properly mixed. Verify that you loaded the correct sample volume to the well. Remove and sonicate or flush the sample probe to remove any clogs.

	Sample probe height is set incorrectly.	Adjust the sample probe height.
	There is a clog in the sample line.	Run the following commands: Backflush, Drain, Alcohol Flush, and Wash.
		Verify that the delta cal temperature is within ± 3.0. If the system is not within these limits, recalibrate, then retry
Sample Empty Detected	The system completely acquired the entire sample volume.	Verify that you properly mixed the samples before dispensing into the wells.
	There is no sample in the designated well.	Verify that you loaded the sample to the correct well on the plate.
		Verify that the sample volume added to the well is correct.
	The probe is clogged.	Clean the sample probe. See “Clean the Sample Probe” on page 6-4.
	The sample probe is not properly aligned.	Align the sample probe. See page B-8.
	There is a clog in the fluid line.	Run the following commands: Backflush, Drain, Alcohol Flush, Wash.
	Delta Cal temp out of range.	Verify that the delta cal temperature is within ± 3.0 degrees. Recalibrate if outside these limits and retry.
	There is a problem with the kit.	Verify that the system is functioning properly by running the system controls. Run system controls. If they pass, contact the kit manufacturer.

Cannot calculate inverse function

This error message encompasses a range of mathematical errors often indicating that the sample result was negative or invalid. This is according to the parameters defined by the formula used to analyze the sample results. Standards, assay controls, and unknowns may all be flagged with Unknown Formula Failure. A standard curve is plotted using the MFI and expected concentration value. An Unknown Formula Failure message may occur when the system is unable to calculate a standard concentration from the standard curve.

You are using the wrong template.	Verify that you are using the correct template. See Templates on page 5-73.
You are using incorrect lot information.	Verify that you have entered the correct lot information. See page 5-28.
There is a problem with the kit.	Run system controls. If they pass, contact the kit manufacturer.

Luminex SD Problems

If the empty sheath fluid container is not replaced and the system continues to operate, the Luminex SD system eventually vents pressure to prevent air from being introduced into the Luminex 100 analyzer. This may interrupt a sample and prevent further samples from being collected.

Filter

If the filter attached to the sheath intake line becomes clogged from extended use, an alarm will sound even though the bulk sheath container is not empty. If this happens, contact Luminex Technical Support for a replacement filter.

Malfunction

If the alarm sounds even though the bulk sheath container has fluid and the sheath filter is in good condition, the system is reporting a malfunction. If this happens, contact Luminex Technical Support.

Draining the Reservoir

If you need to ship the Luminex SD system back to Luminex Corporation, drain the reservoir before you pack the system. Call Technical Support for additional information.

Verification

◆ To verify your system from the Maintenance tab:

1. Vortex xMAP reagent containers to ensure homogeneity.
2. Load a microtiter plate with CON1, CON2, and four wells with sheath fluid in the six desired wells.
3. Click **Eject/Retract**. The plate holder ejects.
4. Place the plate on the plate holder.
5. Fill the Luminex XYP reservoir with a solution of 70% isopropanol or 70% ethanol.
6. Click **Eject/Retract**. The plate holder retracts.
7. If you are using a new lot, click **New Control Targets** from the Maintenance tab, fill in the required information, and click **OK**.
8. Click **Prime**. The **Confirmation** dialog box opens. Click **OK** to begin priming. Wait until the Prime is completed.
9. Click **Eject/Retract** to eject the Luminex XYP instrument tray. Place 70% isopropanol or 70% ethanol in the reservoir. Click **Alcohol Flush**. The **Confirmation** dialog box opens. Click **OK** to begin the Alcohol Flush.
10. Click **OK** and wait until the alcohol flush completes. The **Device Status** section on the Status Bar changes from yellow to green and indicates Standby. This takes about five minutes.
11. Select the well where CON1 is located from Step 2 using the drop-down arrow located to the right of the CON1 button. Verify the location. Click **CON1**. The **Confirmation Screen** dialog box opens. Click **OK**. Wait until CON1 completes.
12. Select the well where CON2 is located from Step 2 using the drop-down arrow located to the right of the CON2 button. Verify the location. Click **CON2**. The **Confirmation Screen** dialog box opens. Click **OK**. Wait until CON2 completes.
13. Verify that the system controls completed successfully from the Diagnostics tab System Monitor. If controls are successful, the date and time appear as green text. If controls fail, the date and time are appear as red text.
14. On the **Maintenance** tab, click the well where you placed the sheath fluid. Click Wash. A confirmation dialog box opens.

15. Click **OK** and wait until the Wash completes. The Device Status section on the Status Bar changes to standby when the Wash cycle is complete. The Run Batch tab indicates if the command succeeded or failed upon completion.

16. Run four WASH commands.

8 Product Numbers

Hardware

Note: These part numbers are subject to change without notice.

Note: Common description of product is enclosed in brackets.

Product Description	Customer Number
Rear Air Filter	CN-0001-01
Bottom Air Filter	CN-0002-01
Air Filter, Intake	CN-0027-01
Alignment guide, XYP instrument	CN-0016-01
Bar Code Scanner	CN-PC03-01
Serial Cable, 5 feet	CN-0005-01
PC, Luminex 100 IS	CN-PC04-01
2 Amp, 250 Volts, Fast Acting Fuse (Qty 10)	CN-0019-01
3 Amp, 250 Volts, Fast Acting Fuse	CN-0051-01
Heater Block, XYP	CN-0017-01
Wrench, Hexdrive, Ball Driver 3/32”	CN-0025-01
Luminex 100 IS, Version 2.3 [complete system]	CN-L005-01
Luminex 100 IS, Version 2.3 [complete system] with laptop	CN-L007-01

Luminex 100 IS Documentation Version 2.3 (Manuals on CD)	CN-M032-01
Luminex 100 IS User Manual, Version 2.3 (North American)	CN-M017-01
Luminex 100 IS User Manual, Version 2.3 (International English)	CN-M018-01
Luminex 100 IS User Manual, Version 2.3 (Danish)	CN-M031-01
Luminex 100 IS User Manual, Version 2.3 (French)	CN-M019-01
Luminex 100 IS User Manual, Version 2.3 (German)	CN-M020-01
Luminex 100 IS User Manual, Version 2.3 (Greek)	CN-M030-01
Luminex 100 IS User Manual, Version 2.3 (Italian)	CN-M022-01
Luminex 100 IS User Manual, Version 2.3 (Spanish)	CN-M021-01
Luminex 100 IS Developer Guide to xMAP Technology Version 2.3	CN-M029-01
Power Cord, USA	CN-P001-01
Power Cord, Australia	CN-P002-01
Power Cord, Brazil	CN-P003-01
Power Cord, Denmark	CN-P004-01
Power Cord, Germany, Sweden, France, Belgium, and Spain	CN-P005-01
Power Cord, Switzerland	CN-P006-01
Power Cord, Israel	CN-P007-01
Power Cord, UK	CN-P008-01
Power Cord, Italy	CN-P009-01
Power Cord, Japan	CN-P010-01
Power Cord, China	CN-P012-01
Reservoir, XYP	CN-0022-01
Sample Needle Height Alignment Kit [Sample Probe Alignment Kit]	CN-0015-01
Short Sample Needle	CN-0006-01
Long Sample Needle	CN-0007-01
Sample Holder, Large, 1.5 mL	CN-0008-01
Sample Holder, Small, 1.2 mL	CN-0009-01
Sheath Filter with Quick Disconnect	CN-0010-01
Sheath Bottle	CN-0011-01
Syringe Cylinder with Seal	CN-0013-01

Syringe Seal (Qty 4)	CN-0014-01
Cable, USB	CN-0018-01
Waste Bottle	CN-0012-01
Luminex SD [Luminex Sheath Delivery System]	CN-S001-01

Software

Product Description	Customer Number
Luminex 100 IS Version 2.3 [Software CD]	CN-SW08-01

xMAP Reagents

Product Description	Customer Number
Microspheres, LX100, CL1 CL2 Calibration (xMAP Classification Calibrator)	L100-CAL1
Microspheres, LX100, RP1 Calibration (xMAP Reporter Calibrator)	L100-CAL2
Microspheres, LX100, CL1 CL2 Control (xMAP Classification Control)	L100-CON1
Microspheres, LX100, RP1 Control (xMAP Reporter Control)	L100-CON2
Sheath Fluid, LX100	40-50000

Training

Product Description	Customer Number
Basic Training Course	CN-0070-01

A Glossary

agglutination	The coalescing of small particles that are suspended in solution; these larger masses are then (usually) precipitated.
ambient temperature	The temperature of the surrounding environment.
analyte	A substance that is detected through assay analysis. Each test or bead set will test for a specific analyte.
analyzer	This term is used to refer to the Luminex 100 analyzer.
APD	Avalanche Photo Diode; Measures the excitation emission intensity of the color coding classification dye mixtures inside the microsphere and the amount of light scattered as particles pass by the lasers.
background (noise)	That portion of a bead set result that can be attributed to excess reporter molecules in the solution, nonspecific binding, or fluorescent spillover from another fluorochrome.
batch	A group of samples that are processed using a selected template.
bead	Shorthand terminology for an xMAP microsphere.
calibration	A process used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel for the Luminex 100 IS. Calibration ensures optimal and consistent microsphere classifications and reporter readings.
calibrators	xMAP microspheres used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel for the Luminex 100 IS.

CL1	Refers to dyes embedded in the microsphere. Also see classification channel.
CL2	Refers to dyes embedded in the microsphere. Also see classification channel.
classification channel	A specific range of wavelengths in which light intensity is measured. Includes the emission of a given classification dye. Classification channels are abbreviated as CL1 and CL2.
control microspheres, assay	Used to verify standards within the kit. Tells you that the curve or thresholds are correct.
control microspheres, system	xMAP microspheres used to verify the calibration and optical integrity for the Luminex 100 analyzer.
cuvette	Principal fluid pathway within the optics component of the system through which the sample is read.
data reduction	The analysis of acquired batch data.
delta cal temperature	The difference between the current temperature of the Doublet Discriminator APD and its temperature at your last calibration. The system displays this value on the Diagnostics tab within the software.
DD temperature	The current temperature of the doublet discriminator avalanche photo diode.
emission spectrum	Wavelength range that an excited fluorochrome emits when its electrons fall from a higher to a lower energy state. Expressed in nanometers (nm).
event	Occurs when the signal processor determines that a particle is being observed. Referred to as one bead as it passes through the laser.
excitation spectrum	Wavelength range that excites a molecule's electrons to a higher energy state. Expressed in nanometers (nm).
fluorescence	Light emission that occurs when the electrons of a fluorochrome drop to a lower energy state.
fluorochrome	A fluorescent molecule.
fluorophore	See fluorochrome.
immunofluorescence	A technique which uses a covalently linked fluorochrome-antibody complex to detect or quantify a particular antigen.

Luminex xMAP microsphere set	Luminex multi-analyte microspheres containing a unique mixture of two distinctly colored fluorochromes to distinguish them from other multi-analyte microspheres.
laser	Light Amplification by Stimulated Emission of Radiation (laser). This highly purified source of light is an efficient way to excite fluorochrome electrons.
microparticle	A solid substance with a diameter in the micrometer range. Often used as a synonym for a microsphere.
microspheres	Polystyrene spheres with a diameter in the micrometer range. Also called beads.
multi-analyte	Several assays or tests performed simultaneously in the same reaction container.
multi-batch	A set of batches to be processed consecutively.
photobleaching	The process in which light absorption converts the fluorochromes inside the beads into different fluorescent or nonfluorescent compounds. Photobleaching prevents beads from being properly classified.
PMT	Photomultiplier tube, measures the excitation emission intensity of the reporter dye bound to the surface of the xMAP microspheres.
qualitative	Pertaining to calculations that determine the absence or presence of an analyte.
quantitative	Pertaining to calculations that determine the precise numerical measurement of an analyte.
reporter	A molecule (or combination of molecules) with a specific range of excitation and emission wavelengths that is used to identify or quantify an analyte. Examples of acceptable reporters for the Luminex 100 IS are Phycoerythrin and Alexa 532.
reporter channel (RP or RP1)	A specific range of wavelengths that includes the emission wavelength of a designated reporter molecule.
RP1	Refers to the dyes bound to the surface of the xMAP microsphere. Also see reporter channel.
RP	See reporter channel.

sample	The mixture of assay components (microspheres, reporter, patient diluent) that are analyzed.
sample reaction	The reaction that occurs between your reagents and the beads.
signal	Detectable measurement unit of the reporter molecule.
standards microspheres, assay	Assay standards are substances of know concentrations used to derive a standard curve with which unknown samples and controls are compared to determine their concentration or quantity. See control microspheres, assay.
suspension	Solution consisting of homogeneously dispersed microspheres in an aqueous medium.
system controls	Include the xMAP reporter and classification control microspheres. They are used to verify the calibration of the Luminex 100 analyzer.
template	A sequence of commands and predetermined settings defined by the kit manufacturer.
verification	The process using system controls to ensure the analyzer is functioning properly with current calibration settings.
xMAP	See Luminex xMAP microsphere set.

B Luminex 100 IS System Installation

Overview

This appendix provides hardware, firmware, and software installation procedures as required for new or system updates. On new systems, the factory preinstalls the latest versions of the firmware and software; you perform only the hardware installation. Upgrades become available for enhancements or to repair a corrupted file. Upgrade instructions or Luminex Technical Support may direct you to sections in this appendix to perform a software or firmware procedure.

If this is a new Luminex 100 IS 2.3 system installation, then only perform the procedure in the following "Luminex 100 IS System Setup" section. Otherwise, perform any of the following procedures as required:

- **Luminex 100 IS System Hardware Setup**—If you are installing the Luminex 100 IS 2.3 system hardware continue with Luminex 100 IS System Setup (page B-1).
- **Luminex 100 IS Software Installation**—If you need to upgrade or reinstall your Luminex 100 IS 2.3 system software, refer to Luminex 100 IS 2.3 Software Installation (page B-14).
- **Luminex Firmware Installation**—If you need to perform a firmware upgrade in your Luminex 100 analyzer, Luminex XYP instrument, or Luminex SD system, refer to Luminex 100 IS 2.3 Firmware Installation (page B-21).

Luminex 100 IS System Setup

Before connecting the system components, ensure that the facility complies with all system and safety requirements. Read the safety information that begins in Warnings and Notes (page 2-2). Position the instrument to minimize temperature fluctuations.

The following sections describe how to connect the Luminex 100 IS system components. An Installation Drawing (page B-27) provides clearances and other related information. Figure B-1 shows the components of the system and how they should be placed.

Perform the following procedures to set up the system. Each of these steps can be found on the page number shown in parentheses:

1. Connect the Luminex 100 analyzer and Luminex XYP to the PC (page B-3)
2. Install the Luminex XYP Instrument Sample Probe (page B-6)
3. Power On System Components (page B-8)
4. Accept the Luminex 100 IS 2.3 Software License Agreement (page B-8)
5. Adjust the Sample Probe Vertical Height (page B-8)
6. Install the Luminex XYP Instrument Reservoir (page B-9)
7. Calibrate and Verify the System (page B-10)
8. Install the SD System (page B-10)
9. Install the Luminex XYP Instrument Heater Block (page B-13)

1. Monitor
2. PC
3. Luminex XYP Instrument
4. Barcode Scanner
5. Luminex SD system
6. Luminex 100 Analyzer

Figure B-1 Luminex 100 IS System Setup

Connect the Luminex 100 analyzer and Luminex XYP to the PC

Caution: Due to the weight of the analyzer, use two people for lifting.

Note: Do not place the PC or monitor on top of the Luminex 100 analyzer or XYP instrument.

You must set up and calibrate the Luminex 100 analyzer and Luminex XYP instrument before you can install the Luminex SD system.

◆ To connect and power on the system:

1. Install the PC and monitor according to the instructions provided by the PC manufacturer. Place the monitor on top of the PC.
2. Unpack the Luminex 100 analyzer and the Luminex XYP instrument. Review Hardware (page 3-2) to verify that each system component came with the system.
3. Place the Luminex XYP instrument on a clean, flat surface to the left of the PC.

Figure B-2 Red Shipping Pin

4. Remove the red shipping pin from the XYP. Leave the silver knob in the Luminex XYP instrument. See Figure B-2.
5. Place the Luminex 100 analyzer onto the Luminex XYP instrument. See Figure B-1 and Figure B-3 for positioning.
6. Thread the alignment guide (translucent plastic tube) through the opening on the Luminex analyzer into the Luminex XYP instrument. See Figure B-3. Adjust the position of the Luminex 100 analyzer with the Luminex XYP instrument until the alignment guide threads screw in completely.

Note: The cable that connects the analyzer to the PC is 5 feet long; the cable that connects the SD to the analyzer is 2.5 feet long.

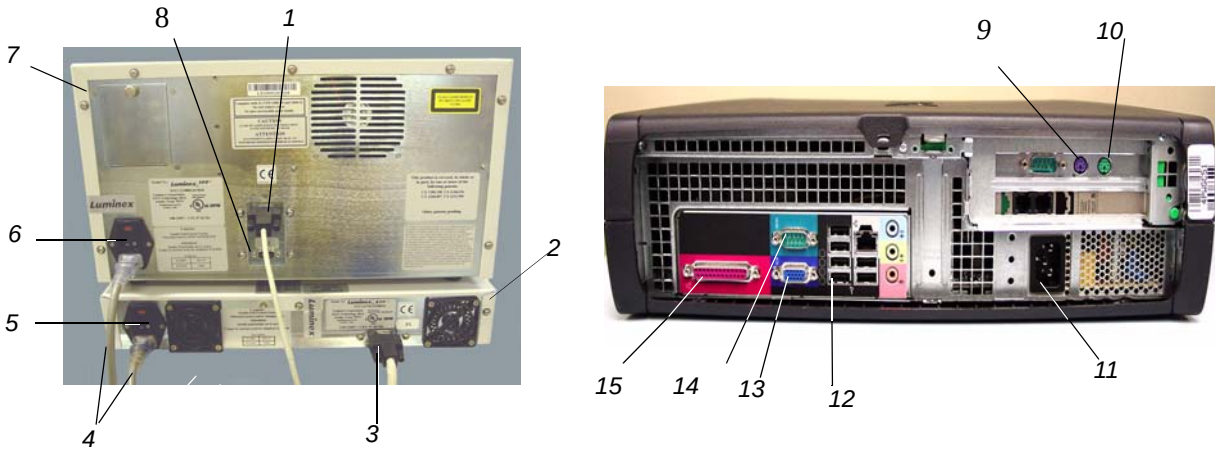
Figure B-3 Install Alignment Guide

7. Ensure that the power switches on the analyzer and XYP instrument are in the off position.

8. Attach the power cord to the power input module of the Luminex XYP instrument and attach the serial cable to the Luminex XYP instrument. Do not plug the Luminex XYP instrument into the power outlet.

9. Attach the power cord to the input module of the Luminex 100 analyzer, then attach the USB cable (PN 85-10011-00-046) to P1 on the analyzer. Do not plug the power cord into the power outlet. See Figure B-4.

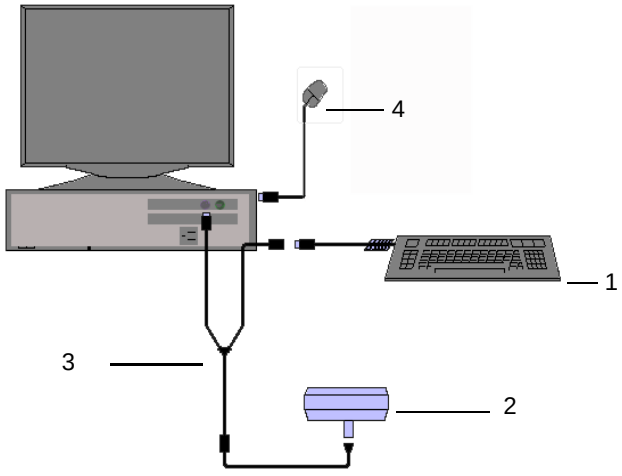
10. Connect the Luminex 100 analyzer USB cable and the Luminex XYP instrument serial cable to the PC. See items 12 and 14 in Figure B-4.



1. USB Communication Cable (P1)
2. Luminex XYP Instrument
3. Luminex XYP Instrument to PC Serial Cable
4. Power Cords
5. Luminex XYP Instrument Power Switch
6. Luminex 100 Analyzer Power Switch
7. Luminex 100 analyzer
8. SD Cable (P2)
9. Y-Cable Port
10. Mouse Cable port
11.PC Power Cable
12. Luminex 100 port (USB)
13. Monitor cable port
14. Luminex XYP port
15. Printer cable port

Figure B-4 Luminex 100 IS Connections (Luminex 100 analyzer, Luminex XYP Instrument, and PC)

11. Connect the Y-cable to the barcode reader and keyboard, then connect the Y-cable to the PC. See Figure B-5.



1. Keyboard
2. Barcode Reader
3. Y-Cable
4. Mouse

Figure B-5 Connecting the PC, Mouse, Barcode Reader, and Keyboard

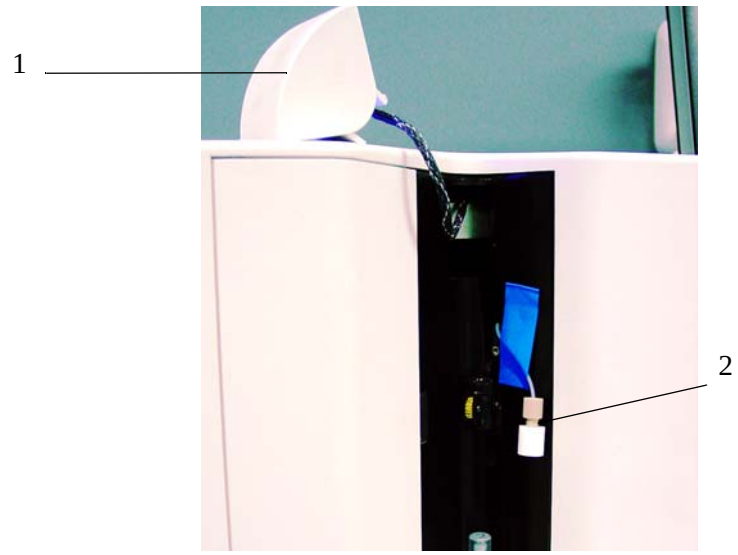
Note: The sheath and waste containers must be placed on the same surface as the Luminex XYP instrument. Do not place the containers on top of the Luminex 100 analyzer.

12. Connect the color-coded tubing connectors to the Luminex 100 analyzer. Blue = sheath, green = air, orange = waste.
13. Fill the sheath bottle with sheath fluid to just below the air intake fitting. Place the sheath and waste containers to the left side of the analyzer. Connect the blue connector to the sheath fitting (bottom fitting) on the sheath bottle. Connect the green connector to the air fitting (top fitting) on the sheath bottle. Connect the orange connector to the waste fitting on the waste bottle.
14. Plug the Luminex XYP instrument, Luminex 100 analyzer, PC, and monitor power cords into approved outlets. We strongly recommend using an uninterruptible power supply to protect the system from power variations. Refer to Recommended Additional Equipment (page 3-7) for additional information.

Install the Luminex XYP Instrument Sample Probe

◆ To install the Luminex XYP instrument sample probe :

1. Verify that the Luminex 100 analyzer and Luminex XYP instrument power switches are off. Unplug them from the electrical outlet.
2. Remove the light housing directly above the sample arm by grasping and firmly pulling out. It remains attached by a wire harness. Place it on top of the analyzer. See Figure B-6.

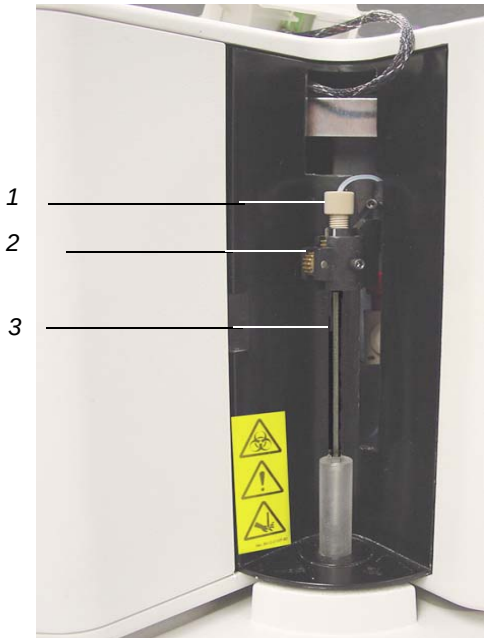


1. Light Housing 2. Cheminert fitting with cap

Figure B-6 Light Housing Removed

3. Unscrew the cap from the Cheminert fitting.

4. Insert the sample probe into the sample probe holder. Insert the Cheminert fitting into the sample probe holder, turning it clockwise. Be careful that the threads are correctly aligned. Hand tighten only. See Figure B-7.



1. Cheminert Fitting
2. Sample Probe Holder
3. Sample Probe

Figure B-7 Insert Sample Probe and Cheminert Fitting

5. Push the light housing back into place.

6. Install the clear plastic shield that covers the sample probe area. See Figure B-8.

Figure B-8 Sample Probe Area with Clear Plastic Shield in Place

7. Plug the Luminex XYP instrument and the Luminex 100 analyzer into an approved outlet.

Power On System Components

Power on the system components:

- The Luminex 100 analyzer (switch on back)
- The Luminex XYP instrument (switch on back)
- The PC and monitor (switches on front)

After you power on the PC, Windows automatically starts up and then the Luminex 100 IS software automatically starts up. Continue with "Configure the Luminex 100 IS 2.3 Software" section.

Accept the Luminex 100 IS 2.3 Software License Agreement

The first time the Luminex 100 IS 2.3 software starts up, you have to acknowledge the License. Read the agreement and click **Accept** to continue.

Adjust the Sample Probe Vertical Height

You must adjust the sample probe vertical height each time you change the type or style of microtiter plate. Since this is a new installation, you need to adjust the sample probe for your microtiter plates. See Figure B-9.

1. Thumb Wheel *2. Height Adjustment Locking Screw*

Figure B-9 Thumb Wheel and Height Adjustment Locking Screw

◆ To adjust the sample probe vertical height:

1. Remove the clear plastic shield that covers the sample probe area.

2. In a 96-well microtiter plate where overall height is no more than 0.75 inches (19 mm), place the appropriate alignment tool in the plate:

   For a standard plate with flat-bottom wells—stack two of the larger (5.08 mm diameter) alignment discs together and place them into the selected well.

   For a filter bottom plate—stack three of the larger (5.08 mm diameter) alignment discs together and place them into the selected well.

   For a half-volume plate with flat-bottom wells—stack two of the smaller (3.35 mm diameter) alignment discs together and place them into the selected well.

   For a round-bottom (U-bottom) plate—stack two of the smaller (3.35 mm diameter) alignment discs and place them into well A1.

   For a plate with conical wells—place one alignment sphere into the selected well.

Note: Alignment discs can be placed in any well as long as the well is designated in the software.

3. Select the **Maintenance** tab, then click **Eject/Retract** to eject the plate holder. Place the 96-well microtiter plate on the Luminex XYP instrument plate holder with position A1 in the top left corner. Click **Eject/Retract** to retract the plate.
4. Use the 3/32 inch hex wrench to loosen the height adjustment locking screw. See Figure B-9.
5. Verify that the correct location is selected with the appropriate number of discs. The location must be the same as indicated in the software or the location you choose. Click **Sample Probe Down** to lower the sample probe.
6. Using the thumb wheel, lower the probe until it just touches the top of the alignment discs or sphere.
7. Use a 3/32 inch hex wrench to tighten the height adjustment locking screw.
8. Click **Sample Probe Up** to raise the sample probe.
9. Replace the plastic shield that covers the sample probe area.

Install the Luminex XYP Instrument Reservoir

Use the Luminex XYP instrument reservoir for the Luminex 100 analyzer maintenance functions.

◆ To install the Luminex XYP instrument reservoir:

1. On the **Maintenance** tab, click **Eject/Retract** to eject the plate holder.
2. Insert the reservoir in the upper-right corner of the plate holder. See Figure B-10.

Figure B-10 The XYP Instrument Reservoir

3. Click **Eject/Retract** to retract the plate holder.

Calibrate and Verify the System

Run system calibration. See Calibration and Verification (page 5-28) to complete the installation process by running the system calibrators and controls.

Install the SD System

◆ To install the Luminex SD system:

1. After performing system calibration and the pressure has stabilized, select **Prime** from the Home or Maintenance tab. Then, at the Diagnostic tab, System Monitor section, record the air and sheath pressure.

   Air pressure: _____ psi.

   Sheath Pressure: _____ psi.

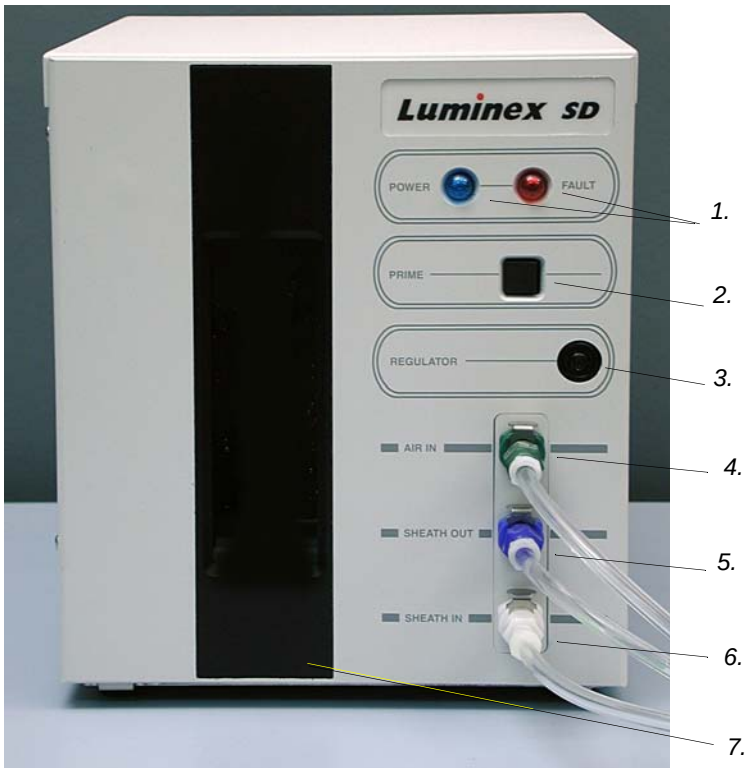
   Save this information. You will need it later in the installation procedure and also if you return to the original sheath fluid and waster bottle configuration.

2. At the end of the Prime cycle, disconnect the sheath fluid bottle. Store it in a safe place. If you plan to use the Luminex SD system waste line, disconnect the waste bottle. Connect the system waste line to the instrument and insert the end into a large waste container.

Note: Do not place the Luminex SD on top of the Luminex 100 Analyzer.

3. Place the Luminex SD system near the sheath fluid connection on the left side of the Luminex 100 analyzer. Make the following connections; refer to Figure B-11 as needed.

   - Connect the sheath fluid line (blue fitting) to the **Sheath Out** connector on the front of the Luminex SD system.
   - Connect the air line (green fitting) to the **Air In** connector on the front of the Luminex SD system.
   - If you are using the Luminex SD system waste line, connect the waste line tubing to the waste connector on the left side of the Luminex 100 analyzer (orange fitting). Place the other end of the waste line into a large waste receptacle. Cut off excess tubing. Ensure the waste receptacle is level with the Luminex 100 analyzer or no more than three feet below it.
   - Connect the sheath fluid intake line (white fitting) to the **Sheath In** connector on the front of the Luminex SD system.



1. Power and Fault indicators
2. Prime button
3. Regulator adjust
4. Air In connector (green)
5. Sheath Out connector (blue)
6. Sheath In connector (white)
7. Reservoir window

Figure B-11 Luminex Sheath Delivery Device

Note: Ensure that the sheath fluid box is at least three feet below the system, otherwise the Luminex SD system will overfill.

- Lower the stainless steel filter end of the sheath fluid line to the bottom of a full 20 liter box of sheath fluid. Secure the cap on the sheath fluid box. Place the sheath fluid container so that the cap is on the top.
- Attach the power cord to the input module on the back of the Luminex SD system. Connect the P1 cable (PN 85-10011-00-068) to the back of the SD and to P2 on the back of the analyzer. Plug the power cord into the power outlet. See Figure B-12.

Figure B-12 Back of SD System, P1 Port

4. Turn on the power to the Luminex SD system; the Luminex SD system automatically primes itself. You hear the Luminex SD system pump turn on. When the Luminex SD reservoir is about 2/3 full, it automatically stops priming.

Note: The regulator must be fully opened to work properly. It is important to make sure that you turn it as far as it will go.

5. Open the center access door on the Luminex 100 analyzer. Use a screwdriver to turn the regulator fully clockwise. This typically takes three to six full turns. Regulator is under arrow as Figure B-13 shows.

Figure B-13 Luminex 100 Analyzer Regulator Adjustment

6. From the Home or Maintenance tab, select **Prime**. During this prime cycle, use a screwdriver to adjust the regulator on the front of the Luminex SD system. See Figure B-13. Adjust it until the sheath pressure displayed on the Diagnostic tab, System Monitor section, reads the same as the sheath pressure you recorded in step 4. The system should stabilize at this sheath pressure. The air pressure should be the same as you recorded in step 4, within 0.1 psi.

   If the Prime cycle ends before you have completed the adjustment, select **Prime** again and continue to adjust the regulator.

7. Calibrate the system again. Observe the sheath pressure displayed on the Diagnostic tab, System Monitor section, during the calibration cycle. The pressure should be within 0.1 psi of the pressure recorded in Step 4.

Follow up with installing the heater block (below), if necessary.

Install the Luminex XYP Instrument Heater Block

Use the Luminex XYP instrument heater block as required by your assay kit instructions. This is an optional step. When not in use, store the heater block in the bracket inside the left access door of the Luminex 100 analyzer.

◆ To install the Luminex XYP instrument heater block:

1. On the **Maintenance** tab**,** click **Eject/Retract** to eject the plate holder.
2. Insert the Luminex XYP instrument heater block on the plate holder. See Figure B-14.

Figure B-14 The Luminex XYP Instrument Heater Block

3. Click **Eject/Retract** to retract the plate holder.
4. Turn the heater on and set the temperature. Refer to Set Luminex XYP Instrument Heater Temperature (page 5-16).

For new system installations, perform the preliminary commands listed in the Prepare System for First Use (page B-26) before running samples.

Luminex 100 IS 2.3 Software Installation

New Luminex 100 IS 2.3 systems arrive with the Luminex 100 IS 2.3 software installed. Upgrading existing systems to Luminex 100 IS Version 2.3 requires that you upgrade your software through an upgrade kit. The upgrade kits include necessary components, such as software CDs, manuals, cables, and instructions.

Select the upgrade kit that applies to your current version or is called out in your upgrade kit procedure. If your current software version is:

- Luminex 100 Version 1.7 with Windows 98 you need Upgrade Kit CN-U010-01. Follow the procedure on page B-15.
- Luminex 100 Version 1.7 with Windows 2000 you need Upgrade Kit CN-U010-06. Follow the procedure on page B-17.
- Luminex 100 IS Version 2.1 or 2.2 you need Upgrade Kit U010-07. Follow the instructions on page B-19.

Luminex 100 Version 1.7 with Windows 98 to Luminex 100 IS Version 2.3

Overview of upgrade to Luminex IS 2.3 software procedure:

- Install new PC
- Install Luminex IS 2.3 software
- Verify successful upgrade.

Install New PC

◆ To install the new PC:

1. Close all applications. Perform a complete system shutdown. Turn the power off and unplug the Luminex 100 analyzer, Luminex XYP, and PC.
2. Remove all connections from the old PC. Remove the old PC and set aside. Place the new PC in place.
3. Connect the monitor, power, and Com cables to the new PC.
4. Install the keyboard into a USB port.
5. Connect the barcode reader to the back of the PC. Connect the mouse to the mouse port. Continue with the Install Luminex 100 IS 2.3 Software section.

Install Luminex 100 IS 2.3 Software

◆ To install the Luminex 100 IS 2.3 software:

1. Turn on power to only the PC and monitor (switches are on the front). The system starts up Windows.
2. Log into Windows as local Administrator:

   a.) In the **Welcome to Windows** dialog box, press **Ctrl+Alt-Delete**.

   b.) In the **Log On to Windows** dialog box, enter **Administrator** in the **User Name** box. In the **Password** box, enter the Administrator password. If you do not know it, see your IT representative or contact Luminex Technical Support. In the **Log on to** box, select the name of your local machine from the scroll list.

   c.) Click **OK** to complete the log on procedure.

   d.) Verify that all applications are closed.
3. Insert the Luminex 100 IS 2.3 software CD into the drive. The CD autoplays and in a few moments displays the Luminex 100 IS 2.3 splash screen. See Figure B-15.

Figure B-15 Luminex 100 IS 2.3 Startup Splash Screen

4. At the **Luminex 100 IS Setup—Welcome** dialog box, click **Next** to continue.

5. At the Luminex **100 IS Setup—License Agreement** dialog box, read the End-User License Agreement (EULA). Use the scroll bar to display all the text. Click **Yes** to continue.

Note: If the system displays a blank screen after it has rebooted, press `Alt+Tab` on the keyboard to display the software on the monitor.

6. At the **Luminex 100 IS Setup—InstallShield Complete** dialog box, remove any floppy disks from their drives and click **Finish**. The system restarts Windows and auto starts the Luminex 100 IS software.

   The first time Luminex 100 IS starts up it displays the End-User License. To continue click **Accept**. Uncheck the **Show Next Time** checkbox to bypass this dialog box on the next startup. If you click Decline the application closes.

Verify Successful Upgrade

1. Start up software. The main screen of the IS software appears.

2. Verify software upgrade information. From the Help menu, click **About the Software**. The About Luminex 100 IS Software dialog box opens. Verify that the version number on your screen begins with 2.3, as shown in Figure B-16. The numbers after the 2.3 do not need to match those in Figure B-16.

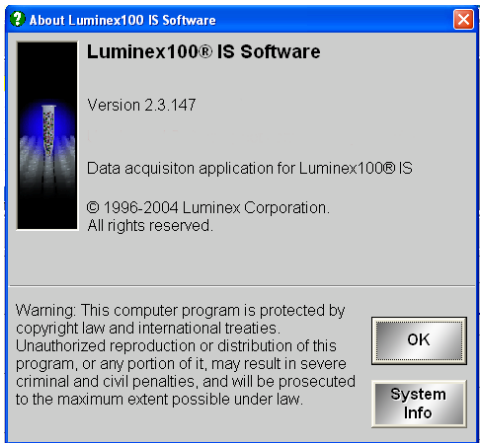


Figure B-16 Software Information Window

3. Run system calibration. See Calibration and Verification (page 5-28) to complete the verification process by running the system calibrators and controls.

Luminex 100 Version 1.7 with Windows 2000 to Luminex 100 IS Version 2.3

To upgrade to Luminex IS 2.3 software you perform these procedures in the following order:

- Optionally, archive your “My Sessions” folder
- Remove LMAT software
- Remove Luminex 100 Version 1.7 software
- Install Luminex IS 2.3 software
- Verify successful upgrade

Archive “My Sessions” folder

To preserve your Luminex 100 Version 1.7 session data, archive your “C:\My Sessions” folder. Copy the files to another folder or save them to a diskette or CD. Luminex 100 IS Version 2.3 software maintains session data in a database, not in the My Sessions folder.

Remove Luminex LMAT Software

Remove the Luminex LMAT software using the Windows Control Panel.

1. On the PC desktop select: **Start⇨Settings⇨Control Panel**. The Control Panel opens on the desktop.
2. Double-click the **Add/Remove Programs** icon. The **Add/Remove Programs** dialog box opens.
3. In the Currently installed programs list, select **LMAT** entry. The entry expands to include the Change/Remove button. Click **Change/Remove**.

Note: During the LMAT software removal, error dialog boxes may open. They are of no consequence to the uninstall. Just click OK or Yes in response and continue with the uninstall.

4. The InstallShield Wizard—Welcome dialog box opens. See Figure B-17.

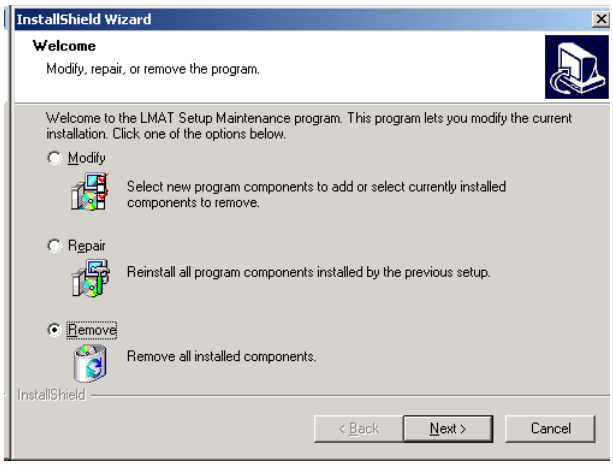


Figure B-17 InstallShield Wizard Dialog Box—Remove

Select **Remove** and click **Next**. The Confirmation File Deletion dialog box opens. Click **OK**.

5. If the Shared File Detected dialog box opens, select **Don't display this message again**, then click **Yes**.

6. If the Registry Editor dialog box opens, click **OK**.

7. When the InstallShield Wizard—Maintenance Complete dialog box opens, click **Finish**. Do not close the Add/Remove Programs dialog box. Continue with the following "Remove Luminex 100 Version 1.7 Software" section.

Remove Luminex 100 Version 1.7 Software

You remove the Luminex 100 Version 1.7 software through the Windows Control Panel.

If you are continuing from the previous section, then skip to step 3.

1. On the PC desktop select: **Start⇨Settings⇨Control Panel**. The Control Panel dialog box opens on the desktop.

2. Double-click the **Add/Remove Programs** icon. The **Add/Remove Programs** dialog box opens.

3. Under the Currently installed programs list, select the **Luminex Data Collector** entry. The entry expands to include the Change/Remove button. Click **Change/Remove**.

4. The **InstallShield Wizard** dialog box opens. Select **Remove** and click **Next**.

Note: During the Luminex 100 Version 1.7 software removal, error dialog boxes may open. They are of no consequence to the uninstall. Just click OK or Yes in response and continue with the uninstall.

5. Click **OK** in the **Confirmation File Deletion** dialog box.

   If a Shared File Detected dialog box opens, select the **Don't display this message again** checkbox, then click **Yes.**

   If a Self-registration error dialog box opens, Click **OK**.

6. When the InstallShield Wizard—Maintenance Complete dialog box opens, click **Finish**.

7. Click **Close** on the Add/Remove Programs dialog box. Click the **X** on the Control Panel to close.

8. If the **LMAT** and the **Luminex Data Collector** icons are still present on the desktop, drag the icons to the Recycle Bin.

Install Luminex 100 IS 2.3 Software

To install the Luminex 100 IS 2.3 software, continue with Install Luminex 100 IS 2.3 Software (page B-15).

Luminex 100 IS Version 2.1/2.2 to Luminex 100 IS Version 2.3

Overview of upgrade to Luminex IS 2.3 procedure:

- Backup your Luminex 100 IS 2.1 or 2.2 database
- Remove Luminex 100 IS Version 2.1 or 2.2
- Install Luminex IS 2.3 software
- Verify successful upgrade.

Backup Luminex 100 IS 2.1 or 2.2 Database

***Important**—Backup your database before you uninstall Version 2.1 or 2.2 software.*

◆ To back up your Luminex 100 IS 2.1 or 2.2 database:

1. On the **Tools** menu, click **Database Backup**. The **Backup Database To...** dialog box opens. See Figure B-18.

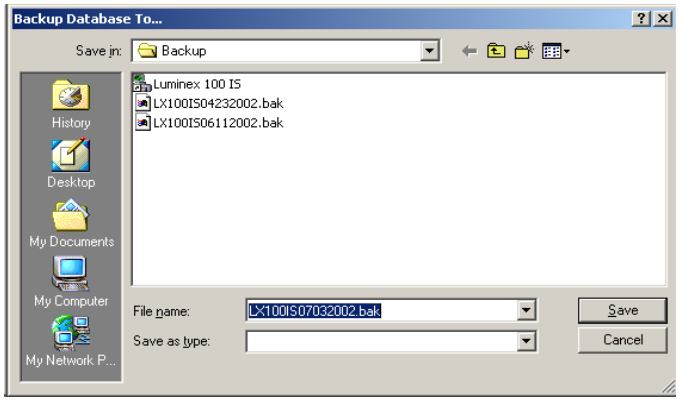


Figure B-18 Backup Database To... Dialog Box

2. Choose the file name and location of the database that you want to back up and click **Save**. The database is backed up and the Backup Database To... dialog box closes. Close the IS Sofware.

Remove Luminex 100 IS 2.1 or 2.2

You remove the Luminex 100 IS Version 2.1 or 2.2 software through the Windows Control Panel.

Note: During the Luminex 100 IS Version 2.1 or 2.2 software removal, error dialog boxes may appear. They are of no consequence to the uninstall. Just click OK or Yes in response and continue with the uninstall.

1. On the PC desktop select: **Start⇨Settings⇨Control Panel**. The Control Panel dialog box opens on the desktop.
2. Double-click the **Add/Remove Programs** icon. The Add/Remove Programs dialog box opens.
3. Under the Currently installed programs list, select the **Luminex 100 IS** entry. The entry expands to include the Change/Remove button. Click **Change/Remove**.
4. The InstallShield Wizard dialog box opens similar to Figure B-17. Select **Remove** and click **Next**.
5. The Confirmation File Deletion dialog box opens. Click **OK**.

   If a Shared File Detected dialog box opens, select the **Don't display this message again** checkbox, then click **Yes.**

   If a Self-registration error dialog box opens, Click **OK**.
6. When the InstallShield Wizard—Maintenance Complete dialog box opens, click **Finish**.
7. In the Add/Remove Programs dialog box, click **Close.** Click the **X** on the Control Panel to close it.
8. If the **Luminex 100 IS** icon is still present on the desktop, select the icon and drag it to the Recycle Bin.

Install Luminex 100 IS 2.3 Software

To install the Luminex 100 IS 2.3 software, continue with Install Luminex 100 IS 2.3 Software (page B-15).

Luminex 100 IS 2.3 Firmware Installation

The Luminex 100 analyzer, the Luminex XYP instrument, and the Luminex SD system use firmware to perform internal control functions. Although seldom required, firmware updates may become available to enhance functionality. If you are directed to update the firmware due to an upgrade kit or other enhancement, follow the appropriate procedure in this section. There is a separate section for the Luminex 100 analyzer, Luminex XYP instrument, and the Luminex SD system. Review the following "Firmware Upgrade Cable Configurations" section, then continue with the desired firmware upgrade section.

Firmware Upgrade Cable Configurations

- **Upgrading a Luminex 100 Version 1.7 system**—If you are upgrading your firmware from a system previously using the Luminex 100 Version 1.7 software (with Windows 98 or 2000):
  - Luminex SD system—If you have the optional Luminex SD system, remove the serial interface cable between the Luminex XYP and the Luminex 100 analyzer, then attach it to the Luminex SD system to perform the firmware upgrade. After completing the SD firmware upgrade, reattach the serial cable to the back of the XYP.Then, replace the serial interface cable with the SD interface cable supplied in the upgrade kit. If you are upgrading the firmware for more than one component (for instance, the SD and the XYP), you must upgrade the SD system first.
  - Luminex 100 analyzer cable—Use the existing serial interface cable between the PC and Luminex 100 analyzer to perform the firmware upgrade. Then, replace the serial interface cable with the USB interface cable supplied in the upgrade kit.
  - Luminex XYP instrument—Continue to use the serial interface cable between the PC and Luminex XYP.
- **Upgrading a Luminex 100 IS Version 2.1/2.2 system**—If you are upgrading a Luminex 100 IS Version 2.1 or 2.2 system:
  - Luminex SD system—Remove the serial interface cable between the Luminex XYP and the Luminex 100 analyzer, then attach it to the Luminex SD system to perform the firmware upgrade. After completing the SD firmware upgrade, reattach the serial cable to the back of the XYP.Then, replace the serial interface cable with the SD interface cable (the shorter cable) supplied in the upgrade kit. If you are upgrading the firmware for more than one component (for instance, the SD and the XYP), you must upgrade the SD system first.
  - Luminex 100 analyzer cable—Continue to use the existing USB interface cable between the PC and Luminex 100 analyzer.

- Luminex XYP instrument—Continue to use the serial interface cable between the PC and Luminex XYP.

Luminex 100 Analyzer Firmware Upgrade

Follow the steps in this section to update and verify the Luminex 100 analyzer firmware.

Perform the Luminex 100 IS Version 2.3 software update before installing firmware upgrade tools and firmware files. See Luminex 100 IS 2.3 Software Installation (page B-14) for the procedure.

Connect Cable

There are two types of interface cable that connect between the Luminex 100 analyzer and the PC; one is a serial cable and the other is a USB cable.

Note: If you are not familiar with connecting the cables refer to Luminex 100 IS System Setup (page B-1).

- To upgrade from Luminex 100 Version 1.7, use the existing serial interface cable. Then, replace with USB cable after the upgrade.
- To upgrade from Luminex 100 IS Version 2.1 or 2.2, use the existing USB cable.

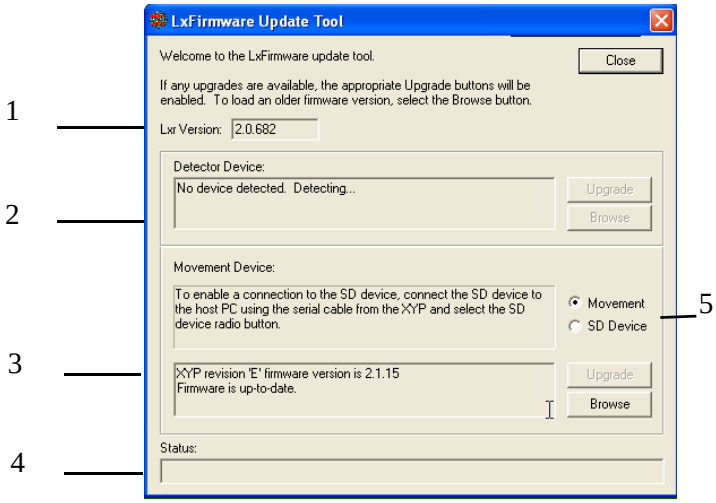
Upgrade Firmware

To upgrade the Luminex 100 analyzer firmware:

1. Close any open applications.
2. On the PC desktop click **Start⇨Programs⇨Luminex⇨LXR⇨LX Firmware.** The LX Firmware Update Tool dialog box opens. See Figure B-19.
3. Notice in the Detector Device text box (item 2 in Figure B-19) that the top line displays the current firmware version and the second line displays the firmware status. That is, either an update is available or the firmware is up-to-date. See note.

   If the second line indicates that the firmware is up-to-date, then click **Close**. No further action is required. If an update version is available, then continue with step 4.

Note: If you are directed by Technical Support or by upgrade kit instructions to upgrade to a specific firmware version, then click the Browse button and select the desired firmware version from the Open dialog box.



1. LXR Runtime Version
2. Luminex 100 analyzer firmware version
3. Luminex XYP / SD instrument firmware version
4. Status of Upgrade
5. Movement Device/SD Device selection button

Figure B-19 LXFirmware Update Tool Dialog Box

Note: If you are upgrading the Luminex XYP instrument firmware consider doing it at this time, then verify the Luminex 100 analyzer and the Luminex XYP instrument at the same time.

4. Click **Upgrade** adjacent to the Detector Device text box. The Confirm LX100 Firmware Download dialog box opens. Click **Yes** to continue with the upgrade. Click **No** to return to the previous dialog box.
5. The Download In Progress dialog box opens displaying the progress. Read the information presented on the dialog box. When the download is finished the Status text box displays **Download Complete**. Click **OK**.
6. Turn off the power for 5 seconds, then turn the power to the Luminex 100 back on.
7. Next verify the upgrade. See note.

Verify Successful Firmware Upgrade

1. Start up the Luminex 100 IS software.
2. On the **Help** menu, click **About the Device**. The About the Luminex 100 & Luminex XYP Devices dialog box opens.
3. Verify that the **Controller Version** entry for the Luminex 100 Device Information section on the dialog box displays the upgrade version.

Update Interface Cable

- If you are upgrading from Luminex 100 Version 1.7 replace the serial interface cable with USB cable supplied in the upgrade.

- If you are upgrading from Luminex 100 IS Version 2.1 or 2.2 continue to use the USB cable.

Luminex XYP Instrument Firmware Update

Follow the steps in this section to update and verify the Luminex XYP instrument firmware.

Update Firmware

To update the Luminex XYP instrument firmware:

1. Close any open applications.
2. On the PC desktop click **Start⇨Programs⇨Luminex⇨LXR⇨LX Firmware.** The LX Firmware Update Tool dialog box opens. See Figure B-19.

Note: If you are directed by Technical Support or by upgrade kit instructions to upgrade to a specific firmware version, then click the Browse button and select the desired firmware version from the Open dialog box.

3. Notice in the Movement Device text box (item 3 in Figure B-19) that the top line displays the current version of the Luminex XYP analyzer firmware and that the second line displays its status. If the second line indicates that the firmware is up-to-date, then click **Close**. No further action is required. If an update version is available, then continue with step 4.
4. Click **Upgrade** adjacent to the Movement Device text box. The Confirm XYP Firmware Download dialog box opens. Click **Yes** to continue with the upgrade. Click **No** to return to the previous dialog box.

Note: If you are upgrading the Luminex 100 firmware, consider doing it at this time, then verify the Luminex 100 analyzer and the Luminex XYP instrument at the same time.

5. The Download In Progress dialog box opens displaying the progress. Read the information presented on the dialog box. When the download is finished the Status text box displays **Download Complete**.
6. Turn the power off for 5 seconds, then turn the power to the XYP back on.
7. Click **OK**. Next verify the upgrade.

Verify Successful Firmware Upgrade

1. Start up the Luminex 100 IS software.
2. On the **Help** menu, click **About the Device**. The About the Luminex100 & Luminex XYP Devices dialog box opens.
3. Verify that the **Controller Version** entry for the Luminex 100 Device Information section on the dialog box displays the version listed in the upgrade document. Your upgrade kit instructions list the correct version number.

Luminex SD System Firmware Update

If you are upgrading the firmware for more than one component (for instance, the SD and the XYP), you must upgrade the SD system first. Follow the steps in this section to update and verify the Luminex SD system firmware.

Update Firmware

To update the Luminex SD system firmware:

1. Close any open applications.
2. Turn off the power to the SD, XYP, and LX100.
3. Remove the serial cable from the Luminex XYP instrument and plug it into P2 on the back of the SD system.
4. Turn power back on to the SD system.
5. On the PC desktop click **Start⇨Programs⇨Luminex⇨LXR⇨LX Firmware.** The LX Firmware Update Tool dialog box opens. See Figure B-19.
6. Select the **SD Device** option button. Notice in the Movement Device text box (item 3 in Figure B-19) that the top line displays the current version of the Luminex SD system firmware and that the second line displays its status.

Note: If you are directed by Technical Support or by upgrade kit instructions to upgrade to a specific firmware version, then click the Browse button and select the desired firmware version from the Open dialog box.

7. If the second line indicates that the firmware is up-to-date, then click **Close**. No further action is required. If an update version is available, then continue with step 8
8. Click **Upgrade** adjacent to the Movement Device text box. The Confirm SD Firmware Download dialog box opens. Click **Yes** to continue with the upgrade. Click **No** to return to the previous dialog box.

Note: If you are upgrading the Luminex XYP instrument firmware consider doing it at this time, then verify the Luminex 100 analyzer and the Luminex XYP instrument at the same time.

9. The Download In Progress dialog box opens displaying the progress. Read the information presented on the dialog box. When the download is finished the Status text box displays **Download Complete**. Click **OK**.
10. Turn off the power for 5 seconds, then turn it back on.

Verify Successful Firmware Upgrade

1. On the PC desktop click **Start⇨Programs⇨Luminex⇨LXR⇨LX Firmware.** The LX Firmware Update Tool dialog box opens. See Figure B-19.
2. An entry in the Movement Device text box should read: **`Firmware up-to-date`**.

3. Turn the power off to the SD, XYP, and LX100.
4. Reconnect the serial cable to the XYP.
5. Connect the SD interface cable to the SD and LX100.
6. Turn on the power to the SD, The XYP, and the LX100.

Network Installation Advisory

Note: The Windows XP security settings “Virus Protection” and “Automatic Updates” alerts have been turned off by default. Please refer to your IT department when connecting to the network. If you have questions, please call Luminex Technical Support.

This section is intended for your network IT representative regarding computer name changes. Luminex does not support network installations. However, if your installation requires that you change the computer name, perform these steps:

◆ To change the computer name on Luminex 100 IS 2.3 systems:

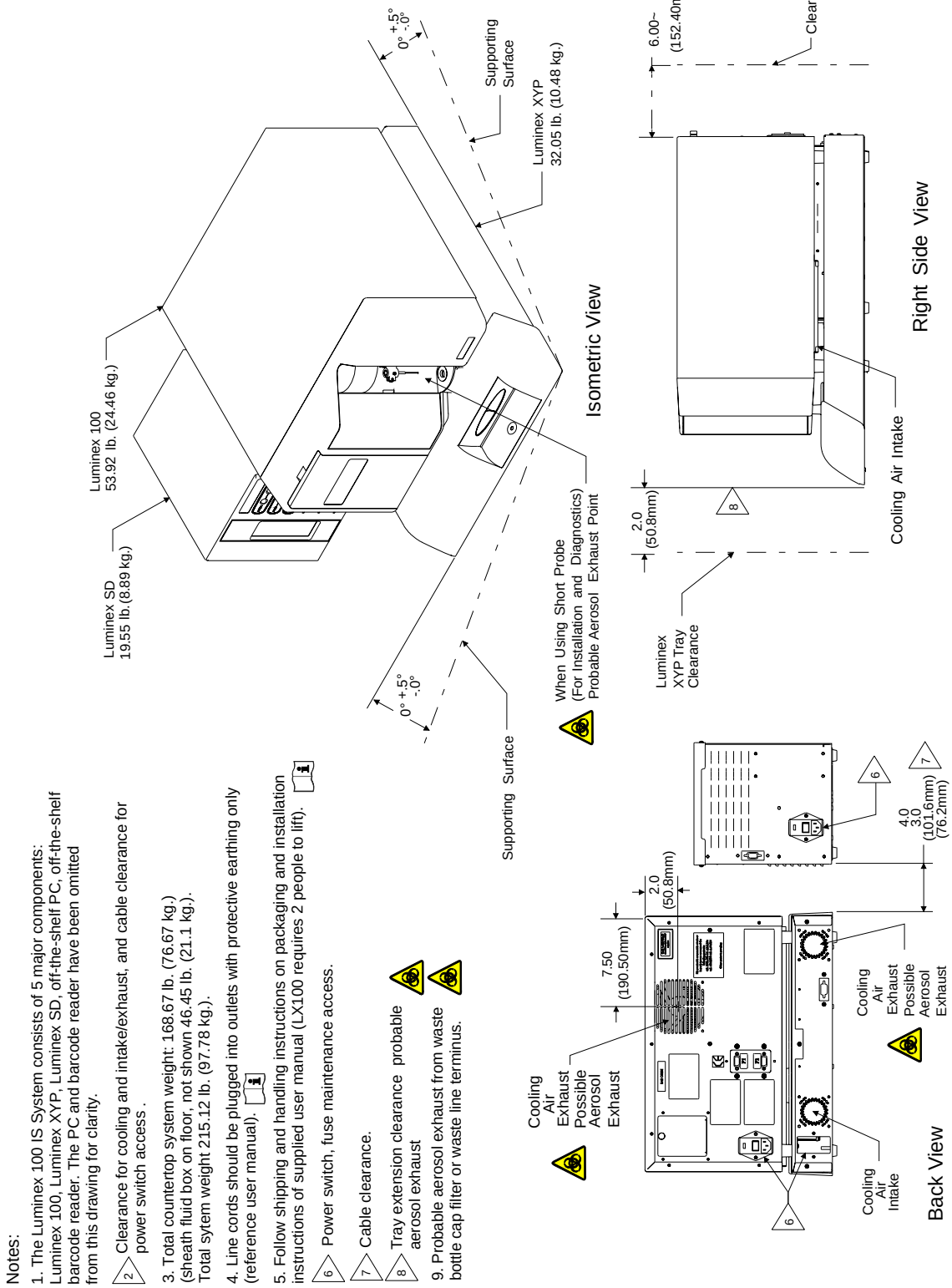
1. Change the computer name following the Windows process.
2. When you reboot the system an error message appears warning about database errors.
3. Reinstall Luminex 100 IS 2.3 software using the Repair option. After the reinstall the database is available; you do not need to reboot.

Prepare System for First Use

After you install the hardware and software, run the following commands to prepare the system for first time use. Also, consider running these commands when the system has been idle for extended periods of time. Refer to Maintenance Commands (page 5-19) for command operation. Run the following commands in order:

- 2 Backflushes
- 2 Drains
- 2 Alcohol flushes
- 3 Washes with water

Installation Drawing



Notes:

1. The Luminex 100 IS System consists of 5 major components: Luminex 100, Luminex XYP, Luminex SD, off-the-shelf PC, off-the-shelf barcode reader. The PC and barcode reader have been omitted from this drawing for clarity.
2. Clearance for cooling and intake/exhaust, and cable clearance for power switch access .
3. Total countertop system weight: 168.67 lb. (76.67 kg.) (sheath fluid box on floor, not shown 46.45 lb. (21.1 kg.). Total sytem weight 215.12 lb. (97.78 kg.).
4. Line cords should be plugged into outlets with protective earthing only (reference user manual).
5. Follow shipping and handling instructions on packaging and installation instructions of supplied user manual (LX100 requires 2 people to lift).
6. Power switch, fuse maintenance access.
7. Cable clearance.
8. Tray extension clearance probable aerosol exhaust
9. Probable aerosol exhaust from waste bottle cap filter or waste line terminus.

C Output.CSV

Overview

This chapter describes the file specification for the Luminex 100 IS 2.3 OUTPUT.CSV file. Although this document may refer to older versions of Luminex software for historical purposes, it is intended only to describe the OUTPUT.CSV file for the Luminex 100 IS 2.3 system. Although this chapter was prepared to ensure accuracy, Luminex assumes no liability for errors or omissions or for damages resulting from the application or use of this information.

The OUTPUT.CSV file was created to provide a simple data report. The file displays general batch information and statistical results. Note that the term Batch is synonymous with Session in other versions of Luminex Software.

Overall Design

The OUTPUT.CSV file contains two blocks of information. The first is the header, which contains general batch information. The second block of information is the results section, which contains several subsections displaying statistical analyses in a Sample versus Test format, as illustrated in the following example:

Batch Header

Results
Stat1
Stat1 Header: Sample Location, Sample Name, Test1, Test2, ..., TestN, Total Count, Notes
Sample1
Sample2
....
SampleM
Stat2
StatN Header: Sample Location, Sample Name, Test1, Test2, ..., TestN, Total Count, Notes
Sample1

Sample2
....
SampleM
StatN
StatN Header: Sample Location, Sample Name, Test1, Test2, ..., TestN, Total Count, Notes
Sample1
Sample2
....
SampleM

Blank Lines

- There is one blank line between the Date and SN fields.
- There are four blank lines between the Operator field (or last optional field) and Samples field.
- There is one blank line between the Samples and Results fields.
- There is one blank line between the Results field and the first statistical data block.
- There is one blank line between each of the statistical data blocks.

Field Definitions

Table D-1 Field Definitions

Field Name	Field Value Description
Program, "value"<,CC>	The name of the Luminex application that created the OUTPUT.CSV file. If the file is generated by a non-US operating system, the country code (in hex) is appended.
Build, "value"	The version of the Luminex application that created the OUTPUT.CSV file.
Date, "date", "time"	The date & time that the OUTPUT.CSV file was created. This field is not related to batch execution time. Note that the date and time values are separated into distinct, adjacent fields ("Date","04/14/2003","02:46:45 PM") to maintain compatibility with previous versions of software.
SN, "value"	The serial number of the Luminex 100 device with which the batch was executed.
Session, "value"	The name of the batch. The term Session was used here to maintain compatibility with previous versions of software. Limited to 30 characters.
Operator, "value"	The name contained in the Current User field on the General tab of the Options dialog in the Luminex 100 IS software.
TemplateID, "value"	(Optional) The database ID that is unique to the template used to create the batch.

Table D-1 Field Definitions (Continued)

Field Name	Field Value Description
TemplateName, "value"	(Optional) The name of the template used to create the batch. Limited to 30 characters.
TemplateVersion, "value"	(Optional) The version of the template used to create the batch. Limited to 10 characters.
TemplateDescription, "value"	(Optional) The description of the template used to create the batch. Limited to 200 characters.
TemplateDevelopingCompany, "value"	(Optional) The name of the company that developed the template used to create the batch. Limited to 30 characters.
TemplateAuthor, "value"	(Optional) The name of the person who created the template used to create the batch. Limited to 30 characters.
SampleVolume, "value"	(Optional) The sample volume defined in the template for sample acquisitions. Units = microliters.
DDGate, "value"	(Optional) The DD gate defined in the template for sample acquisitions
SampleTimeout, "value"	(Optional) The sample timeout defined in the template for sample acquisitions. Units = seconds.
BatchAuthor, "value"	(Optional) The name of the person who created the batch. Limited to 30 characters.
BatchStartTime, "date time"	(Optional) The date & time that the batch was started.
BatchStopTime, "date time"	(Optional) The date & time that the batch was finished.
BatchDescription, "value"	(Optional) The batch description. Limited to 200 characters.
BatchComment, "value"	(Optional) Comment entered after the batch has run.
CALInfo:	(Optional) Indicates the start of the CAL1 & CAL2 machine calibration information logged just prior to and anytime during batch acquisition
CONInfo:	(Optional) Indicates the start of the CON1 & CON2 machine verification information logged just prior to and anytime during batch acquisition
AssayLotInfo:	(Optional) Indicates the start of the Lot information for any standards and/or controls associated with the batch
Samples,"num", MinEvents,"0"	"Samples indicate the number of samples run in the batch. The MinEvents field is unused and will always be zero. Note that this field is adjacent to the Samples field ("Samples","28","Min Events","0"), rather than below it to maintain compatibility with previous versions of software.
Min Events	See Samples field above

Table D-1 Field Definitions (Continued)

Field Name	Field Value Description
Results	This field has no associated value. It is used to indicate the beginning of the statistical results section of the OUTPUT.CSV file.
DataType:,"type"	This field is the name of the statistic represented in the Sample (versus the Test data block immediately below this field). Possible values for DataType include: Median, Result, Count, Mean, %CV, Peak, Std Dev, Trimmed Count, Trimmed Mean, Trimmed %CV, Trimmed Peak, Trimmed Std Dev, and Avg Result. See Table 2 - Statistics Definitions
CRC Entry	(Optional) CRC indicator for the file data. Used to detect external changes to the file.

Statistics Definitions

Statistical calculations are performed for each test in each sample. The number of events to collect for each test in a sample is defined in the template from which the batch was created. In any equations listed below, N indicates the number of events that were collected for an individual test in a single sample. The trimmed distribution represents the events that were collected for an individual test in a single sample with the lowest 5% and highest 5% of the data points removed to help eliminate outliers.

Table D-2 Statistics Definitions

Statistic	Description
Median	The middle value in the distribution of data
Result	The final test result based on a qualitative or quantitative analysis. This value could have units associated with it, as defined in the template. It may also indicate some error condition in the analysis, such as the sample was beyond the range of the curve fit, a divide by zero error occurred, etc. Some example include: - "Invalid" - the user invalidated this sample, or a single test within a sample - "<10 pg/mL" - the result could not be calculated because it fell outside the valid range of the curve fit - ">10000 pg/mL" - the result could not be calculated because it fell outside the valid range of the curve fit - "ERROR" - some mathematical error occurred, such as an MFI value that does not intersect the concentration curve. N/A - a result is not applicable for this sample (i.e. a background sample)
Count	The number of data points in the distribution (N). The number of gated events that fell within the test's specified region.
Mean	(Optional) The sum of the data points in the distribution divided by the number of data points. Mean = $\Sigma x_i / N$

Table D-2 Statistics Definitions

Statistic	Description
%CV	(Optional) The measure of relative dispersion within the distribution. %CV = 100 x Std Dev / Mean
Peak	(Optional) The value that is equal to the largest number of data points within the distribution. For example in data set {1,2,2,3,3,3,4,5}, 3 is the peak because it occurs the most number of times in the distribution list.
Std Dev	(Optional) The measure of dispersion within the distribution. Std Dev = $((N\Sigma x_i^2 - \Sigma x_i)^2 / N (N-1))^{1/2}$
Trimmed Count	(Optional) The number of data points in the trimmed distribution (N_t).
Trimmed Mean	(Optional) The sum of the data points in the trimmed distribution divided by the number of data points. Trimmed Mean = $\Sigma x_i / N_t$
Trimmed %CV	(Optional) The measure of relative dispersion within the trimmed distribution. Trimmed %CV = 100 x Trimmed Std Dev / Trimmed Mean
Trimmed Peak	(Optional) The value that is equal to the largest number of data points within the trimmed distribution.
Trimmed Std Dev	(Optional) The measure of dispersion within the trimmed distribution. Trimmed Std Dev = $((N_t \Sigma x_i^2 - \Sigma x_i)^2) / N_t (N_t -1))^{1/2}$
Avg Result	(Optional) The average of any replicate samples' final test results based on a qualitative or quantitative analysis.

Statistics Column Definitions

The blocks of statistical data are displayed such that the first row of data represents the column headers and the following rows represent the samples that were acquired for the batch.

Table D-3 Statistic Column Definitions

Column Name	Description
Location	The location of the sample in terms of the command list sequence (1, 2, 3,...), the well placement (A1, B1, C1, ...) or both (1(A1), 2(B1), 3(C1), ...)
Sample	The name of the sample as defined in the batch setup. Limited to 30 characters.
Test1, Test2, … , TestN	The number of test columns following the Sample column will depend on the number of tests defined in the Template used to create the batch. Each of the test columns will contain the test name for any given test. Therefore if the Template has 3 tests named Protein A, Protein B and Protein C, then these names will appear in the 3 test column headers in the OUTPUT.CSV file. Limited to 30 characters.

Table D-3 Statistic Column Definitions

Column Name	Description
Total Events	The number of events that fell with in the defined DD gate and into one of the defined regions for a test in the batch. For example, if a template had 3 tests defined and the batch had counts of 100, 102 and 105 for the tests, then the total count would be 307, even though more events may have been detected that did not fall within the DD gate or one of the defined regions.
Notes	Sample notes

Luminex 100 IS OUTPUT.CSV file with no additional features enabled

"Program","Luminex 100 IS",409
"Build","2.3 BETA"
"Date","7/28/2004","2:12:01 PM"

"SN","LX10001298011BE"
"Session","Bead 22 Quant Batch"
"Operator","Joe User"

"Samples","8","Min Events","0"

"Results"

"DataType:","Median"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","57","75",""
"2","Std m","525","75",""
"3","Std l","4341","75",""
"4","Std xl","14316","75",""
"5","Std xxl","25694","75",""
"6","Low Control","58","75",""
"7","Patient 1","532","75",""
"8","Patient 2","14567","75",""

"DataType:","Result"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","2.99 pg/mL","75",""
"2","Std m","15.79 pg/mL","75",""
"3","Std l","126.71 pg/mL","75",""
"4","Std xl","616.93 pg/mL","75",""
"5","Std xxl","3194.84 pg/mL","75",""
"6","Low Control","3.02 pg/mL","75",""
"7","Patient 1","15.98 pg/mL","75",""
"8","Patient 2","636.38 pg/mL","75",""

"DataType:","Count"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","75","75",""
"2","Std m","75","75",""
"3","Std l","75","75",""
"4","Std xl","75","75",""
"5","Std xxl","75","75",""
"6","Low Control","75","75",""
"7","Patient 1","75","75",""
"8","Patient 2","75","75",""

Luminex 100 IS OUTPUT.CSV file with all additional features enabled

"Program","Luminex 100 IS"

"Build","2.3 BETA"

"Date","7/28/2004","2:16:30 PM"

"SN","LX10001298011BE"

"Session","Bead 22 Quant Batch"

"Operator",""

"TemplateID","4"

"TemplateName","Quant Batch"

"TemplateVersion","2.3c"

"TemplateDescription","IS 2.3.137"

"TemplateDevelopingCompany","Luminex"

"TemplateAuthor","MAC"

"SampleVolume","50 uL"

"DDGate","8000 to 15000"

"SampleTimeout","50 sec"

"BatchAuthor","<Name>"

"BatchStartTime","7/28/2004 2:06:44 PM"

"BatchStopTime","7/28/2004 2:10:50 PM"

"BatchDescription","Software Testing"

"BatchComment","Batch Comment for "Bead 22 Quant Batch". This field should be used for general batch information entered by the end user. "

"CALInfo:"

"ProductName","ProductNo","LotName","ExpirationDate","CalibrationTime","BoardTemp","DDTemp","CL1Temp","CL2Temp","Pressure","DDVolts","CL1Volts","CL2Volts","RP1Volts","DDRVal","CL1RVal","CL2RVal","Passed","MachineSerialNo"

"Classification Calibrator","L100-CAL1","A4206","06/07/2006 12:00:00 AM","07/28/2004 09:39:32 AM","26.5625","25.26","25.04","25.26","6.3","74.04","81.33","62.83","-1","556","719","450","True","LX10001298011BE",

"Reporter Calibrator","L100-CAL2","A4071","02/18/2006 12:00:00 AM","07/28/2004 09:43:01 AM","26.7795138888889","-1","-1","-1","6.3","-1","-1","-1","590.5","-1","0","-1","True","LX10001298011BE",

"CONInfo:"

"ProductName","ProductNo","LotName","ExpirationDate","VerificationTime","GatedBeads","MachineSerialNo","Passed"

"Classification Control","L100-CON1","A4153","04/13/2006 12:00:00 AM","07/28/2004 09:45:39 AM","5222","LX10001298011BE","True",

"Reporter Control","L100-CON2","A4137","04/06/2006 12:00:00 AM","07/28/2004 09:52:49 AM","4345","LX10001298011BE","True",

"AssayLotInfo:"

"ManufacturerName","ProductName","ProductNo","ProductType","LotName","ExpirationDate"

"LMNX","Quant Kit","200","Assay Standard","B22std","08/01/2006 11:59:59 PM",

"LMNX","Quant Kit","200","Assay Control","B22con","08/02/2006 11:59:59 PM",

"Samples","8","Min Events","0"

"Results"

"DataType:","Median"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","57","75",""
"2","Std m","525","75",""
"3","Std l","4341","75",""
"4","Std xl","14316","75",""
"5","Std xxl","25694","75",""
"6","Low Control","58","75",""
"7","Patient 1","532","75","Sample Comment for Patient 1."
"8","Patient 2","14567","75","Sample Comment for Patient 2."

"DataType:","Result"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","2.99 pg/mL","75",""
"2","Std m","15.79 pg/mL","75",""
"3","Std l","126.71 pg/mL","75",""
"4","Std xl","616.93 pg/mL","75",""
"5","Std xxl","3194.84 pg/mL","75",""
"6","Low Control","3.02 pg/mL","75",""
"7","Patient 1","15.98 pg/mL","75","Sample Comment for Patient 1."
"8","Patient 2","636.38 pg/mL","75","Sample Comment for Patient 2."

"DataType:","Count"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","75","75",""
"2","Std m","75","75",""
"3","Std l","75","75",""
"4","Std xl","75","75",""
"5","Std xxl","75","75",""
"6","Low Control","75","75",""
"7","Patient 1","75","75","Sample Comment for Patient 1."
"8","Patient 2","75","75","Sample Comment for Patient 2."

"DataType:","Mean"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","240.733333333333","75",""
"2","Std m","503.213333333333","75",""

"3","Std l","4450.92","75",""
"4","Std xl","13478.6666666667","75",""
"5","Std xxl","24817.8933333333","75",""
"6","Low Control","60","75",""
"7","Patient 1","561.12","75","Sample Comment for Patient 1."
"8","Patient 2","14402.3466666667","75","Sample Comment for Patient 2."

"DataType:","%CV"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","662.071761559013","75",""
"2","Std m","42.0677216044823","75",""
"3","Std l","28.540875012004","75",""
"4","Std xl","30.4524100927965","75",""
"5","Std xxl","17.3369506373774","75",""
"6","Low Control","34.9506301308939","75",""
"7","Patient 1","27.7364540209588","75","Sample Comment for Patient 1."
"8","Patient 2","28.9726898443063","75","Sample Comment for Patient 2."

"DataType:","Peak"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","45","75",""
"2","Std m","447","75",""
"3","Std l","3985","75",""
"4","Std xl","3176","75",""
"5","Std xxl","12044","75",""
"6","Low Control","58","75",""
"7","Patient 1","430","75","Sample Comment for Patient 1."
"8","Patient 2","371","75","Sample Comment for Patient 2."

"DataType:","StdDev"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","1593.82742065973","75",""
"2","Std m","211.690384143302","75",""
"3","Std l","1270.33151408429","75",""
"4","Std xl","4104.5788483744","75",""
"5","Std xxl","4302.66591643698","75",""
"6","Low Control","20.9703780785363","75",""
"7","Patient 1","155.634790802404","75","Sample Comment for Patient 1."
"8","Patient 2","4172.74723003512","75","Sample Comment for Patient 2."

"DataType:","Trimmed Count"
"Location","Sample","Test 22","Total Events","Notes"

"1","Std s","69","75",""
"2","Std m","69","75",""
"3","Std l","69","75",""
"4","Std xl","69","75",""
"5","Std xxl","69","75",""
"6","Low Control","69","75",""
"7","Patient 1","69","75","Sample Comment for Patient 1."
"8","Patient 2","69","75","Sample Comment for Patient 2."

"DataType:","Trimmed Mean"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","56.9855072463768","75",""
"2","Std m","494.463768115942","75",""
"3","Std l","4466.08695652174","75",""
"4","Std xl","13634.5217391304","75",""
"5","Std xxl","25095","75",""
"6","Low Control","58.8695652173913","75",""
"7","Patient 1","551.36231884058","75","Sample Comment for Patient 1."
"8","Patient 2","14594.7391304348","75","Sample Comment for Patient 2."

"DataType:","Trimmed %CV"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","23.9771317653444","75",""
"2","Std m","26.4392256987905","75",""
"3","Std l","20.718201051022","75",""
"4","Std xl","25.4309644452528","75",""
"5","Std xxl","14.0816389192424","75",""
"6","Low Control","22.0787072692933","75",""
"7","Patient 1","21.231629005304","75","Sample Comment for Patient 1."
"8","Patient 2","20.5061473536575","75","Sample Comment for Patient 2."

"DataType:","Trimmed Peak"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","45","75",""
"2","Std m","447","75",""
"3","Std l","3985","75",""
"4","Std xl","3715","75",""
"5","Std xxl","15788","75",""
"6","Low Control","58","75",""
"7","Patient 1","430","75","Sample Comment for Patient 1."
"8","Patient 2","8163","75","Sample Comment for Patient 2."

"DataType:","Trimmed StdDev"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","13.6634901596136","75",""
"2","Std m","130.732391650918","75",""
"3","Std l","925.292874765645","75",""
"4","Std xl","3467.39037575852","75",""
"5","Std xxl","3533.78728678387","75",""
"6","Low Control","12.9976389750536","75",""
"7","Patient 1","117.063202011273","75","Sample Comment for Patient 1."
"8","Patient 2","2992.81871196887","75","Sample Comment for Patient 2."
"DataType:","Avg Result"
"Location","Sample","Test 22","Total Events","Notes"
"1","Std s","2.99 pg/mL","75",""
"2","Std m","15.79 pg/mL","75",""
"3","Std l","126.71 pg/mL","75",""
"4","Std xl","616.93 pg/mL","75",""
"5","Std xxl","3194.84 pg/mL","75",""
"6","Low Control","3.02 pg/mL","75",""
"7","Patient 1","15.98 pg/mL","75","Sample Comment for Patient 1."
"8","Patient 2","636.38 pg/mL","75","Sample Comment for Patient 2."
-- CRC --
CRC32: A398CCAD

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